UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE: ORAL PHENYLEPHRINE MARKETING AND SALES PRACTICES LITIGATION	MDL No. 3089 Case No. 1:23-md-3089
THIS DOCUMENT APPLIES TO: All Cases	**INTITIAL STREAMLINED CONSOLIDATED NEW YORK BELLWETHER CLASS ACTION COMPLAINT**

Plaintiffs[1] Sandra Yousefzadeh, Anntwanette Jones, Daniel Calzado, Eli Erlick, John Sloughter, Keith Mortuiccio, Pedro Urena, Kimberly McNulty, and Tatyana Dekhtyar (collectively, "Plaintiffs"), individually and on behalf of all other similarly situated consumers (the "Class," as more fully defined herein), upon personal knowledge as to themselves and their own acts, and as to all other matters upon information and belief, allege as follows:

I. INTRODUCTION

1. Defendants know—and have long known—that the over-the-counter, orally ingested phenylephrine-containing products ("PE Products"[2]) that they manufactured, marketed, represented, warranted, and sold to consumers for the purpose of relieving nasal and sinus

[1] Pursuant to the Court's April 16, 2024 Order, this complaint is a bellwether complaint, filed under New York law, "alleging representative examples of the conduct and claims [Plaintiffs] allege to be at issue in this Multidistrict Litigation relating, among other things, to the marketing and labeling of oral phenylephrine products." ECF 197 at ¶ 1. It has further been ordered that "to the extent the Court grants or denies Defendants' motion to dismiss based on preemption and/or primary jurisdiction, the order will apply to all cases in this Multidistrict Litigation or otherwise subject to transfer into this Multidistrict Litigation." *Id.* at ¶ 4.

[2] To be clear, all references to PE Products refer to products consumed orally and not those administered non-orally, *e.g.*, topical, nasal, or intravenous products. While no PE Products are effective at relieving congestion, a collection of labels of PE Products at issue in this bellwether complaint is contained in Exhibit A, attached hereto. An entirely comprehensive list of all PE products sold during the class period is in the possession, custody, and control of Defendants.

congestion, do not relieve nasal or sinus congestion. Those products include: Sudafed PE (Johnson & Johnson Consumer Inc. ("Johnson & Johnson")); Mucinex Sinus Max (RB Health (USA) LLC ("RB")); Advil Sinus Congestion & Pain (Haleon U.S. Holdings L.L.C. ("Haleon")); NyQuil Severe Cold & Flu (Procter & Gamble Company ("P&G")); up & up Daytime Severe Cold & Flu Softgel (Target Corporation ("Target")); and hundreds of others.

2. Notwithstanding that knowledge, Defendants made a business decision to lie to consumers and sell PE Products anyway. They affirmatively misrepresented and misbranded their PE Products to consumers as effective decongestants on every box sold and in every marketing representation they made, and never disclosed to consumers on any packaging, label, or in any marketing representation, what they knew to be true: that their PE Products do not decongest.

3. The purportedly decongesting ingredient in the PE Products is no more effective at decongesting than a placebo.

4. By at least 2016, that fact – that the PE Products are no more effective at decongesting than a placebo – was unequivocally confirmed by science.

5. Even after an FDA advisory committee composed of leading experts in pharmacological science in September 2023 voted *unanimously*, 16-0, that these products have no efficacy, Defendants are still manufacturing, marketing, representing, warranting, and selling the ineffective products to consumers based upon the same false and misleading information, and without ever disclosing the truth.

6. As the FDA explained in a briefing document authored by FDA scientists for the 2023 meeting of the FDA's Nonprescription Drug Advisory Committee, at least three studies were published, completed, or terminated between 2015 and 2017 that represented "by far the largest and most carefully constructed trials that have ever been performed to evaluate the decongestant

effect of oral PE…and they confirm that orally administered PE is *not effective at any dose* that can be developed and still provide a reasonable margin of safety."[3]

7. Defendants knew about these studies because this issue was widely followed in the industry. Nevertheless, Defendants sold over a billion dollars' worth of PE products every year, all while knowing that those products are no better than placebo at decongesting and *even though Defendants marketed and sold (and continue to market and sell) them to do exactly that*.

8. Indeed, since the science solidified by 2016, Defendants actively conspired to mislead American consumers, and conspired together—including, but not limited to, through the industry's national trade association, Consumer Health Products Association ("CHPA")—to mislead consumers regarding phenylephrine's efficacy and the value of their PE Products.

9. Simply put, for purposes of inducing consumers to purchase their PE Products, Defendants: (a) affirmatively misrepresented the most important and material facts directly to consumers regarding the efficacy of their PE Products; and/or (b) misbranded their PE Products directly to consumers; and/or (c) fraudulently concealed from and/or failed to disclose to consumers material facts regarding the efficacy of their PE Products.

10. Defendants reaped a huge windfall as a result of their deception: current estimates are approximately $1.8 billion of sales of PE Products in 2022 alone, and at least $12 billion in the aggregate sales throughout the Class Period (defined below).

11. Defendants' conduct violates New York consumer protection, fraud, and warranty law, and federal law.

[3] NCAC Briefing Document: Oral Phenylephrine in the CCABA Monograph, Nonprescription Drug Advisory Committee Meeting, September 11 and 12, 2023 at 32 (emphasis added). As explained below, the "NDAC Briefing Document" is a document prepared by FDA scientists for the Non-Prescription Drug Advisory Committee and contains a comprehensive analysis of studies and available data regarding the efficacy of oral phenylephrine.

12. Federal law requires Defendants to ensure that their drug labels remain accurate, and when new scientific information renders their labels *in*accurate, federal law requires Defendants to act. Failure to do so renders their products misbranded.

13. New York law requires the same. Companies are required to describe accurately what they sell to consumers. Defendants, by manufacturing, marketing, representing, warranting, and selling products as effective decongestants when they know that those products do not actually decongest, violated—and continue to violate—New York law.

14. In addition, Defendants that are CHPA members associated together and acted in concert through an enterprise, including through CHPA, to conspire over the course of many years to deceive and fraudulently suppress the truth regarding the efficacy of their products. That conduct constituted a scheme to defraud and conspiracy prohibited by the Racketeer Influenced and Corrupt Organizations Act ("RICO").

15. Plaintiffs are all New York consumers who purchased PE Products during the Class Period and who would not have bought them or would have paid less for them had Defendants disclosed the truth. They filed this litigation on behalf of themselves and all New York consumers who purchased the PE Products to hold Defendants to account for their fraud, to recover as damages the money they spent as a result of that fraud, and to obtain an injunction ordering Defendants to stop falsely marketing the PE Products.

II. JURISDICTION & VENUE

16. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, because Plaintiffs' claims arise under RICO, 18 U.S.C. § 1962 (c) and (d). The Court has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367(a) because the state law claims arise out of the same case or controversy as the RICO

claims. This Court also has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d)(2), because: (a) there are at least 100 class members; (b) the matter in controversy exceeds $5 million, exclusive of interest and costs; and (c) at least one plaintiff is a citizen of a different state than at least one defendant.

17. This Court has personal jurisdiction over Defendants pursuant to 18 U.S.C. § 1965(d) because Defendants maintain minimum contacts with New York State, and intentionally avail themselves of the laws of the United States and New York State by conducting a substantial amount of business in New York State. Defendants continuously and systematically place goods into the stream of commerce for distribution in New York State, sell the PE Products to people in New York State, and engage in wholesale of the PE Products to retailers they know will resell in New York State. Because of Defendants' conduct as alleged in this lawsuit, PE Products were sold to and purchased by individuals in New York State. Alternatively, and for the same reasons, this Court has specific personal jurisdiction over any non-domiciliary Defendants because jurisdiction over such Defendants satisfies the requirements of both New York's long-arm statute (CPLR §302(a)(1)) and of constitutional due process.

18. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(2). A substantial part of the events or omissions giving rise to the claims herein occurred in this judicial district. Venue is also proper because the Judicial Panel on Multidistrict Litigation centralized proceedings in the Eastern District of New York.

III. PARTIES

19. Plaintiff Sandra Yousefzadeh ("Yousefzadeh") is a citizen of the State of New York who, within the last three years purchased in New York the PE Product Sudafed PE® Sinus

Pressure + Pain Maximum Strength, manufactured and/or labeled by Defendant Johnson & Johnson.

20. Plaintiff Anntwanette Jones ("Jones") is a citizen of the State of New York who, within the last three years, purchased the following PE Products in New York: "Vicks® Dayquil™ SEVERE Honey Cold & Flu," manufactured and/or labeled by Defendant P&G; "Equate Children's Multi-Symptom Cold Liquid, Very Berry," manufactured and/or labeled by Defendant Walmart; and "Delsym® Children's Cough+ Cold Nighttime Berry Flavored Liquid," manufactured and/or labeled by Defendant RB Health (US) LLC.

21. Plaintiff Daniel Calzado ("Calzado") is a citizen of the State of New York who in the last three years purchased in New York the PE Product "Vicks NyQuil™ SEVERE Maximum Strength Cold & Flu Berry Flavored Liquid Medicine," manufactured and/or labeled by Defendant P&G. Within the applicable class period, Calzado also purchased the following PE Products manufactured and/or labeled by CVS Health: "CVS Health Non-Drowsy Nasal Decongestant PE Maximum Strength" and "CVS Health Non-Drowsy Sinus PE Pressure, Pain + Cold." Within the class period, Calzado also purchased the PE Product "Advil Multi-Symptom Cold & Flu" manufactured and/or labeled by Defendant Haleon.

22. Plaintiff Eli Erlick ("Erlick") is a citizen of the State of New York who, in the last three years, purchased the following PE Products in New York: Acetaminophen Day/Night Time Vapor Ice Cold and Flu Relief Caplets - 24ct - up & up™ manufactured and/or labeled by Target; TYLENOL® Cold + Flu Severe For Day And Night, manufactured and/or labeled by Defendant Johnson & Johnson; and "Vicks NyQuil Severe Cold & Flu, 24 Liquicaps, Maximum Strength," manufactured and/or labeled by Defendant P&G.

23. Plaintiff John Sloughter ("Sloughter") is a citizen of the State of New York who, in the last three years, purchased in New York the PE Product "Vicks DayQuil SEVERE Honey Flavored Maximum Strength Cold & Flu Liquid," manufactured and/or labeled by Defendant P&G.

24. Plaintiff Keith Mortuiccio ("Mortuiccio") is a citizen of the State of New York who, in the last three years, purchased in New York the following PE Products: "Mucinex Maximum Strength Sinus-Max® Day & Night" manufactured and/or labeled by Defendant RB and its parent Reckitt Benckiser; "TYLENOL® Cold + Flu Severe" manufactured and/or labeled by Defendant Johnson & Johnson; "Mucinex Maximum Strength Fast-Max Severe Congestion & Cough," manufactured and/or labeled by Defendant RB and its parent Reckitt Benckiser; "Vicks DayQuil™ and NyQuil™ VapoCOOL SEVERE Maximum Strength Cold & Flu + Congestion Relief Liquid Co-Pack," manufactured and/or labeled by Defendant P&G; Mucinex Maximum Strength Fast-Max® Day Cold & Flu and Night Cold & Flu," manufactured and/or labeled by Defendant RB and its parent Reckitt Benckiser, Vicks DayQuil™ and NyQuil™ SEVERE Maximum Strength Cough, Cold & Flu Relief LiquiCaps™ Co-Pack manufactured and/or labeled by Defendant P&G.

25. Plaintiff Pedro Urena ("Urena") is a citizen of the State and City of New York who, in the last three years, purchased the following PE Products in New York: "Alka-Seltzer Plus Severe Cold & Flu" manufactured and/or labeled by Defendant Bayer HealthCare LLC; "Thearaflu Daytime Severe Cold Relief Berry Burst Flavor Hot Liquid Powder" manufactured and/or labeled by Defendant Glaxo SmithKline; and "Vicks DayQuil™ SEVERE Maximum Strength Cold & Flu Daytime Relief LiquiCaps" manufactured and/or labeled by Defendant P&G.

26. Plaintiff Kimberly McNulty ("McNulty") is a citizen of the State of New York who, in the last three years, purchased the PE Products "up & up Daytime Severe Cold & Flu Softgel"

manufactured and/or labeled by Defendant Target; "Walgreens Multi-Symptom Children's Cold Liquid" manufactured and/or labeled by Defendant Walgreens; "Walgreens Daytime Severe Cold & Flu Maximum Strength," manufactured and/or labeled by Defendant Walgreens; CVS Health Children's Day + Nighttime Cold, Cough + Congestion Relief Liquid manufactured and/or labeled by Defendant CVS; and "CVS Health Non-Drowsy Daytime Multi-Symptom Cold/Flu Relief Softgels," manufactured and/or labeled by Defendant CVS.

27. Plaintiff Tatyana Dekhtyar ("Dekhtyar") is a citizen of the State of New York who, within the Class Period, purchased the following PE Product in New York: Advil Sinus Congestion & Pain, manufactured and/or labeled by Haleon.

28. Defendant Bayer HealthCare LLC ("Bayer") is a Delaware limited liability company with its principal place of business in Morristown, New Jersey. Bayer manufactures and sells PE Products under the Alka-Seltzer Plus brand name.

29. Defendant CVS Pharmacy Inc. ("CVS") is a Rhode Island corporation with its principal place of business in Woonsocket, Rhode Island. CVS sells and on information and belief manufactures PE products under the CVS brand name.

30. Defendant Haleon plc is an English corporation with its principal place of business in Weybridge, England.

31. Defendant Haleon U.S. Capital LLC (f/k/a GlaxoSmithKline U.S. Capital LLC) is a Delaware limited liability company with its principal place of business in Warren, New Jersey. Haleon US Capital LLC is a subsidiary of Haleon plc.

32. Defendant Haleon US Holdings LLC ("Haleon") (f/k/a GSK Consumer Healthcare Holdings (US) LLC) is a Texas limited liability company with its principal place of business in

Warren, New Jersey. Haleon manufactures and sells PE Products under the Advil, Robitussin, and Theraflu brand names.

33. Defendant Johnson & Johnson Consumer Inc. ("Johnson & Johnson") is a New Jersey corporation with its principal place of business in Skillman, New Jersey. Johnson & Johnson manufactures and sells PE Products under the Sudafed and TYLENOL® brand names.

34. Defendant Kenvue Inc. ("Kenvue") is a Delaware corporation with its principal place of business in Skillman, New Jersey. Kenvue, Inc. is the corporate parent of Johnson & Johnson.

35. Defendant Perrigo Company plc ("Perrigo") is an Irish corporation with its principal place of business in Allegan, Michigan. Perrigo manufactures and sells PE Products under the "Good Sense" brand name.

36. Defendant RB Health (US) LLC ("RB") is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. RB manufactures and sells PE Products under the Delsym and Mucinex brand names.

37. Defendant Reckitt Benckiser LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Reckitt Benckiser LLC is the corporate parent of RB.

38. Defendant Reckitt Benckiser Pharmaceuticals, Inc. (n/k/a Invidior, Inc.) is a wholly owned subsidiary of Reckitt Benckiser Group plc, with its principal place of business in North Chesterfield, Virginia.

39. Defendant Target Corporation ("Target") is a Minnesota corporation with its principal place of business in Minneapolis, Minnesota. Target sells and on information and belief manufactures PE Products under the up & up brand name.

40. Defendant The Procter & Gamble Manufacturing Company ("P&G") is an Ohio corporation with its principal place of business in Cincinnati, Ohio. P&G manufactures and sells PE products under the Vicks brand name.

41. Defendant Walgreen Company ("Walgreens") is an Illinois corporation with its principal place of business in Deerfield, Illinois. Walgreens sells and on information and belief manufactures PE products under the Walgreens brand.

42. Defendant Walmart, Inc. ("Walmart") is a Delaware corporation with its principal place of business in Bentonville, Arkansas. Walmart sells and on information and belief manufactures PE products under the Equate brand name.

43. Defendants Bayer, Haleon, P&G, RB, Johnson & Johnson, Walmart, Target, Walgreens, and CVS shall also be referred to collectively as the "State Law Defendants."

IV. FACTUAL ALLEGATIONS

A. History Of Oral Phenylephrine's Use And Approval

44. In 1972, the FDA implemented an administrative process to review over-the-counter drugs through rulemaking divided by therapeutic class. The process, often referred to as "DESI" for Drug Efficacy Study Implementation, involved convening Advisory Panels respecting each therapeutic class. The panel reports would be published in the Federal Register as Advanced Notice(s) of Proposed Rulemaking, and, after FDA review, a Tentative Final Monograph for each therapeutic class would be issued. After the Tentative Final Monograph was issued, the FDA would move forward with a Final Monograph for each class. Drugs included in the Final Monograph are referred to as "Generally Recognized As Safe and Effective," or "GRASE."

45. One of the advisory panels that met was the "Advisory Review Panel on Over-the-Counter Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Products" ("the Cold-Cough

Panel"). Among many other drugs, the Cold-Cough Panel reviewed Phenylephrine Hydrochloride ("PE" or "phenylephrine") in 1976. The Cold-Cough Panel reviewed a number of studies submitted in the 1970s, which were based on study dates ranging from the 1940s to the 1970s ("the early studies"). As FDA reviewers would later explain, all but one of the early studies submitted to the 1976 reviewers regarding PE's efficacy "evaluated extremely small sample sizes, none adequately controlled for bias, none adequately controlled for multiplicity, and none performed appropriate sample size calculations."[4]

46. The Cold-Cough Panel recognized that the data presented to it were "not strongly indicative of efficacy,"[5] but, in the absence of a safety concern at the suggested dose, nevertheless recommended that oral PE be recognized as "safe and effective" at a dose of 10mg.

47. Following the Cold-Cough Panel's recommendation, PE was included in the Temporary Final Monograph regarding nasal decongestants in 1985 and incorporated into the Final Monograph in 1994. No significant studies of PE's efficacy were published during this interval.

48. That is unsurprising, because few manufacturers used PE in oral nasal decongestants at this time. Instead, the market was dominated by drugs formulated around two other active ingredients: phenylpropanolamine and pseudoephedrine.

[4] NDAC Briefing Document: Efficacy of Oral Phenylephrine as a Nasal Decongestant, Non-Prescription Drug Advisory Committee Meeting, September 11 and 12, 2023; Division of Nonprescription Drugs 1, Office of Nonprescription Drugs, Division of Inflammation and Immune Pharmacology, Office of Clinical Pharmacology, Division of Epidemiology II, Office of Surveillance and Epidemiology, ("NDAC Briefing Document") at 22.
[5] *Id*. at 22.

B. Phenylpropanolamine Removed From The Market And Pseudoephedrine Placed Behind The Counter

49. One of the three compounds in oral nasal decongestants that was evaluated in 1976 and sold over-the-counter was phenylpropanolamine (sometimes called PPA). In 2000, however, a large study from the Yale School of Medicine published in the *New England Journal of Medicine* determined that phenylpropanolamine consumption led to an increased risk in hemorrhagic stroke among certain populations of women.[6] For this reason, over-the-counter decongestants offered for sale in the United States have not contained phenylpropanolamine since at least 2005.

50. The third compound in oral nasal decongestants evaluated by the Cough-Cold panel was pseudoephedrine, which is highly effective. It became well known, however, that pseudoephedrine could be used in the manufacture of methamphetamine. In March 2006, President Bush signed the Combat Methamphetamine Epidemic Act of 2005 (Public Law 109-177). Among other things, the Combat Methamphetamine Act required that retailers move pseudoephedrine products behind the pharmacy counter, and consumers who wish to purchase pseudoephedrine-containing drugs are now often required to present identification and are limited in the amount that they can purchase.

51. As a consequence, by 2006, the PE Products became the *only* over-the-counter drug "intended" to treat nasal congestion that was available for purchase without the hassle of going "behind the counter." The manufacturers responded to this "behind-the-counter" requirement for pseudoephedrine by reformulating their oral nasal decongestant products, producing hundreds of different PE Products for sale.

[6] Kernan, *et al.*, Phenylpropanolamine and the Risk of Hemorrhagic Stroke 343 N. Engl. J. Med. 25 (Dec. 2000), available at https://www.nejm.org/doi/full/10.1056/NEJM200012213432501

52. Whereas before 2006 the vast majority of over-the-counter drugs being sold purportedly to treat nasal decongestion were formulated around pseudoephedrine, by 2007, more PE Products were being sold than pseudoephedrine products, a trend that would continue. As of 2022, consumers purchased approximately five times the number of units of PE Products than pseudoephedrine products (which are behind the counter).

53. Of course, phenylephrine's efficacy had never been scientifically established, and existing data were "not strongly indicative of efficacy."[7]

C. In 2007 The FDA Advisory Committee Explains Further Studies Needed Regarding Phenylephrine's Efficacy

54. In February 2007, Leslie Hendeles, PharmD, Randy Hatton, PharmD, and Almut Winterstein, PhD submitted a Citizen's Petition to the FDA, recommending that the FDA amend the dosages of phenylephrine to allow an increased maximum dose to 25mg (as opposed to the approved 10mg) for adults and children over 12 years of age, and noting that a meta-analysis that they conducted of the early studies resulted in a different conclusion than the original Cough-Cold Panel: namely, that the orally administered phenylephrine was likely no better than placebo at the monographed doses.

55. The FDA's Nonprescription Drug Advisory Committee ("NDAC")—the modern equivalent of the first Cough-Cold Panel—met in December 2007 to consider the issues raised in the February 2007 Citizen's Petition, as well as materials submitted to the committee by Merck/Schering-Plough, a PE Product manufacturer, and the Consumer Health Products Association ("CHPA"), an industry organization.

56. Merck/Schering-Plough presented evidence to the NDAC that the amount of phenylephrine actually left to do "decongesting" after ingestion (the so-called "bioavailability" of

[7] NDAC Briefing Document at 22.

the drug) was less than 1%. This differed considerably from the outdated science that had estimated 38% bioavailability. Merck/Schering Plough appeared to have concerns about efficacy of approved dosages, but hoped to manufacture and market drugs with higher dosing.[8]

57. The CHPA, for its part, presented its own meta-analysis (using studies that the FDA would later characterize as deeply flawed) to compete with the meta-analysis presented by the Citizen's Petition.

58. At the meeting, Dr. Stan Lin, a member of the FDA's Division of Biometrics in the FDA Office for Translational Sciences, reviewed the materials submitted and concluded that neither the Citizens' Petition's nor the CHPA's meta-analysis was conclusive, and noted, in summary, that the studies that had been done on phenylephrine were inadequate. As the FDA would later explain: "Dr. Lin noted that the small size, the lack of multicenter presentation, the lack of reproducibility, and the problematic nature of the methodology used by the original studies evaluated by the Panel suggests that the data underlying the original recommendation made by the Cough-Cold Panel are not conclusive."[9]

59. FDA's presentation to the NDAC further explained that previous studies had determined efficacy by analyzing test subjects' "nasal airway resistance" (NAR) following the use of the drug, but that measurement of a patient's "subjective symptom score" would be better.[10] As the FDA's scientists would later explain, the analysis of NAR to determine whether a decongestant drug is effective is "no longer accepted by the Agency because it is highly variable and unreliable as a measure of congestion,"[11] and has not been an accepted metric since the 1990s.[12]

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[8] *Id*. at 25
[9] *Id*. at 30.
[10] *Id*. at 28-29
[11] *Id*. at 32.
[12] *Id*. at 56.

60. The NDAC did not recommend any major change in 2007. Instead, nine of the twelve panel members sitting in 2007 found that, "due to the limitations of the data" available, it was recommended that "additional clinical data would be necessary, including new studies that should evaluate the decongestant effect of higher doses of oral PE."[13] The NDAC further recommended that future studies evaluate the effectiveness of oral PE using a different methodology; i.e., the measurement of a patient's "subjective symptom scores" rather than the measurement of NAR. Consistent with this recommendation, the FDA subsequently abandoned NAR as the primary endpoint to evaluate congestion in pivotal trials in favor of total nasal symptoms scores.[14]

D. By 2016, Phenylephrine Was Proven Ineffective By New Scientific Evidence

61. Following the Panel's 2007 meeting, further studies were conducted, *not one* of which supports the notion that PE works to decongest. They, in fact, proved the opposite: PE is not effective as a nasal decongestant when taken orally, even at higher doses.

62. Indeed, a number of studies were published following the 2007 meeting (a number published in peer-reviewed journals), all of which showed PE to be ineffective as a decongestant. The studies include at least the following:

- Horak, *et al., A placebo-controlled study of the nasal decongestant effect of phenylephrine and pseudoephedrine in the Vienna Challenge Changer*, 102 Ann. Allerg. Asthma & Immunol. 2 (February 2009), finding that "**Phenylephrine was not significantly different from placebo**" while finding the control group, which was given pseudoephedrine, did experience improved symptoms when compared to placebo.

- Day, *et al*., *Efficacy of loratadine montelukast on nasal decongestion in patients with season allergic rhinitis in an environmental exposure unit*, *Ann Allergy Asthma Immunol.* 2009; 102:328, finding that **"[t]here were no statistically significant differences between phenylephrine and placebo for any measures."**

[13] NDAC Briefing Document at 30.
[14] FDA, 2018, Guidance for Industry; Allergic Rhinitis: Developing Drug Products for Treatment. NAR has not been the primary endpoint variable for approval of prescription cough-cold drugs since the 1990s. *See* NDAC Briefing Document at 56.

- Melzer, *et al*., *Oral Phenylephrine Hcl for Nasal Congestion in Seasonal Allergic Rhinitis: A Randomized, Open-label, Placebo-controlled Study*, J. Allergy Clin Immunol. Pract (Sept-Oct 2015), after studying 507 test subjects, determining that phenylephrine **"at doses of up to 40 mg every 4 hours, is not significantly better than placebo at relieving nasal congestion in adults with [seasonal allergic rhinitis].**"

- Melzer, *et al*, *Phenylephrine hydrochloride modified-release tablets for nasal congestion: a randomized, placebo-controlled trial in allergic rhinitis patients*, 116 J. Ann Allergy Asthma Immunol. 66-71 (Jan 2016), finding that **30mg "modified release" tablets were "not more efficacious than placebo in relieving nasal congestion caused by allergic rhinitis."**

- Johnson and Johnson Phase 2 Study, 2017-2018. In a randomized, double-blind, placebo-controlled, parallel group study of individuals with colds, **"[n]o benefit" was observed from using phenylephrine when compared to placebo**.[15]

63. As the FDA's scientists would explain in a 2023 briefing document created for the NDAC, referring to the 2015 Meltzer study, 2016 Meltzer study, and the 2017-18 Johnson & Johnson study:

> Data from three large, adequately controlled clinical trials conducted subsequent to the 2007 NDAC meeting are now available….**They demonstrate a lack of efficacy with oral [Immediate Release] doses [of phenylephrine] up to 40 mg as well as [Extended Release] doses of 30 mg.** Merck (formerly Schering Plough) conducted two trials in subjects with allergic rhinitis to evaluate (and presumably potentially market) both higher than monographed doses of [Immediate Release] product and a 30 mg product, and Johnson and Johnson conducted a trial in subjects with colds to evaluate (and presumably potentially market) a 30 mg [Extended Release] oral PE product. All used clinically acceptable designs and nasal congestion symptom scores as primary endpoints. **These three trials represent by far the largest and most carefully constructed trials that have ever been performed to evaluate the decongestant effect of oral PE**…. Importantly, none of the three demonstrated any significant difference between monographed doses of oral PE, doses of up to 40 mg of oral [Immediate Release Phenylephrine] (four-fold higher than the monographed dose)…or two different 30 mg [Extended

[15] The Johnson & Johnson study was not published in a peer-reviewed journal. The study, which was conducted with subjects who had colds, had planned to enroll 450 subjects, but ultimately enrolled 193 subjects, at which point an interim analysis was conducted and the study was terminated. The study protocol makes clear that there was to be a "futility analysis"; i.e., a determination regarding whether enrolling additional subjects was actually necessary, or would be "futile" in changing the result. It is apparent that, following the futility analysis, enrolling additional subjects would not change the clear result: oral phenylephrine is no better than placebo. Johnson & Johnson's study protocol for this study is available here: https://cdn.clinicaltrials.gov/large-docs/26/NCT03339726/Prot_000.pdf

> Release] formulations (two trials), compared with placebo. **We believe that these new clinical pharmacology and clinical data are consistent, substantial, and believable, and they confirm that orally administered PE is not effective at any dose that can be developed and still provide a reasonable margin of safety**.[16]

64. In other words, phenylephrine's efficacy had finally been studied in a systematic and in-depth manner, and by 2016, with the Melzer studies, the Day study, and the Horak study, the result was clear: PE is no better than a placebo at decongesting. Even a study by one of PE Products' biggest sellers—Defendant Johnson & Johnson—confirmed as much in 2017-2018.

65. Defendants, as manufacturers and/or sellers of PE Products, were well aware of all of these published studies (and likely their own internal data). By 2016, there was no doubt that oral phenylephrine is no better than placebo at relieving congestion.

66. Moreover, following the FDA's decision to abandon NAR as the primary endpoint to evaluate congestion in pivotal trials in favor of nasal congestion symptom scores, Defendants knew that that the NAR data from the seven original studies that had supported the inclusion of PE in the monograph as "suggestive of efficacy" were no longer supportive of such a claim.

E. Despite Knowing Phenylephrine Is No Better Than Placebo, Defendants Continue To Market and Sell Billions Of Dollars' Worth Of PE Products

67. Despite a scientific consensus by 2016 that phenylephrine is, in the words of one industry-sponsored study, "not more efficacious than placebo,"[17] and their knowledge by 2018 that NAR data could no longer be used to support claims of PE's effectiveness, Defendants took no steps to disclose to consumers that fact, and elected to continue to manufacture, market, represent, warrant, and sell PE Products with deceptive and false labeling, and represent to consumers that PE Products are effective in relieving congestion.

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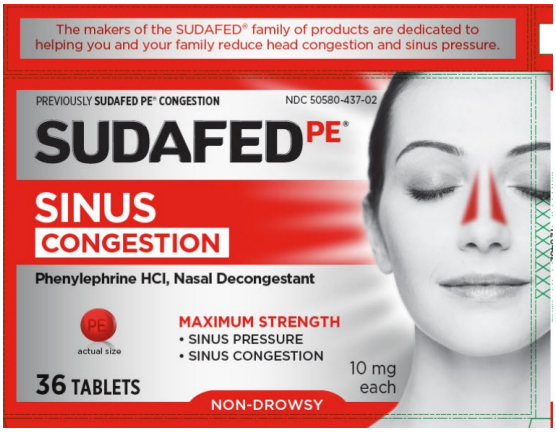
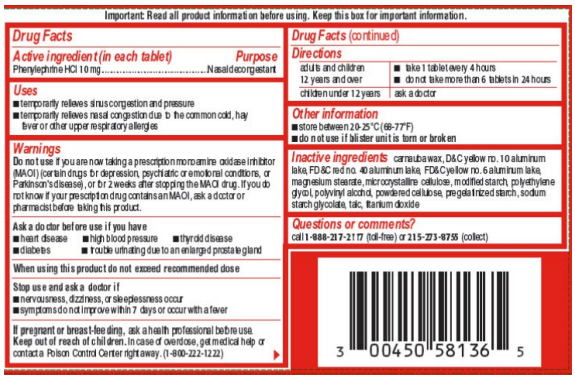
[16] NDAC Briefing Document at 32 (emphasis added).
[17] Melzer, *et al*., Phenylephrine hydrochloride modified-release tablets for nasal congestion: a randomized, placebo-controlled trial in allergic rhinitis patients, 116 J. Ann Allergy Asthma Immunol. 66-71 (Jan 2016)

68. For example, Defendant Johnson & Johnson continues to sell the product Sudafed PE. It affirmatively indicates that phenylephrine relieves "sinus pressure" and "sinus congestion," and goes so far as to call its product "Maximum Strength," despite the product having been proven by multiple studies—including at least two peer reviewed studies and one study *by Johnson & Johnson itself*—to have no efficacy greater than placebo (much less pseudoephedrine); *i.e.*, no strength at all.[18]





69. Sudafed PE remains on the market. And it is not alone. As set forth in Exhibit A, which contains copies of labels for Defendants' PE Products (including but not limited to the PE Products purchased by Plaintiffs), each of the Defendants named herein has marketed and sold and

[18] To be clear, the Final Monograph for OTC Nasal Decongestant Drug products does not include language that PE Products are "extra strength." As shown in Exhibit A, many defendants employ similar "maximum strength" language.

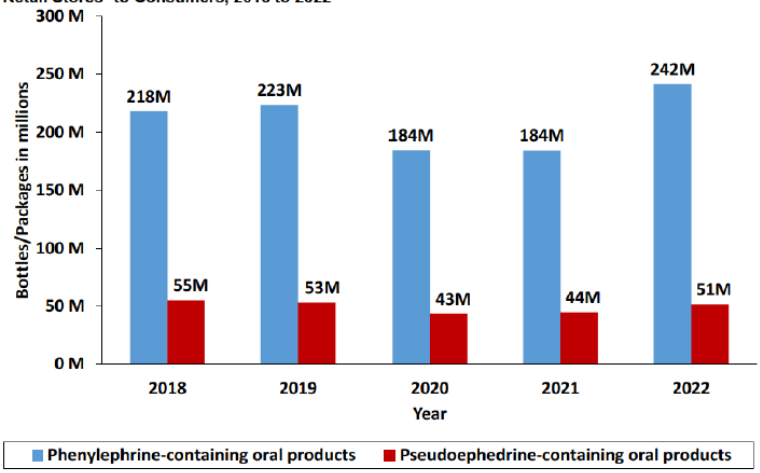
continues to market and sell PE Products as "decongestants" where the sole purportedly "decongesting" ingredient in the product is phenylephrine—the compound Defendants have each known since at least 2016 is no more effective at decongesting than placebo.

70. Many of these same Defendants' PE Products *also* include claims that those PE Products are of "maximum strength," despite the products having no efficacy at all.[19]

71. This is big business. The FDA recently estimated that in 2022 alone, approximately 242 million units of PE Products were sold in the United States, representing approximately $1.8 billion in retail sales in 2022. The FDA further estimates that between 2018-2022, Defendants sold at least 1.05 billion bottles or packages of PE Products.[20] As the FDA has also explained, those sales compensate for the move of pseudoephedrine "behind the counter":

NDAC Briefing Document: Oral Phenylephrine in the CCABA Monograph

Figure 26. National Annual Estimates of Bottles/Packages Sold for Over-the-Counter (OTC) Cough/Cold/Allergy Oral Products Containing Phenylephrine or Pseudoephedrine From U.S. Retail Stores[1] to Consumers, 2018 to 2022



Source: OTC International Market Tracking and Private Label Ingredient Level Report, 2018-2022. Data extracted February 2023.
[1] Retail sales data do not capture sales activity from Costco, convenience stores, specialty stores, internet sales, phone sales or kiosks.

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[19] As detailed below, Plaintiffs Yousoufsadeh, Jones, Calzado, Erlick, Sloughter, Mortuiccio, Urena, and McNulty, each purchased products by Johnson & Johnson, P&G, RB, Walgreens, and CVS that claim to be "maximum strength" or "max strength." Indeed, the claim that phenylephrine-based oral decongestants could be "maximum strength" is particularly absurd and misleading in a world where other non-prescription pseudoephedrine oral decongestants exist—*i.e.*, products that unequivocally work better.

[20] NDAC Briefing Document at 70.

[21] *Id.*

72. According to a recent analysis of data provided by the Pharmacy Benefit Manager, IQVIA, between 2012 and 2021 there were 732 distinct PE Products for sale, with 21 stand-alone products and 711 so-called "combination products," *i.e.*, products in which phenylephrine is included as the ingredient in the product that purportedly relieves congestion, but other substances, such as acetaminophen, are combined into the same product in order to address other symptoms.

73. All the while, Defendants did nothing to disclose to consumers that PE Products do not decongest, and continued to make false representations to consumers that phenylephrine could be used to relieve nasal and sinus congestion, despite knowing full well that it does no such thing.

F. In September 2023, NDAC States What Defendants Already Knew for Years: Phenylephrine Has No Efficacy

74. On July 12, 2023, the FDA announced that it was convening a meeting of the NDAC to discuss new data regarding the effectiveness of oral phenylephrine on September 11-12, 2023.

75. When FDA scientists analyzed all studies and available data, they drafted a comprehensive briefing document summarizing the science (the "NDAC Briefing Document"), which reached an "initial conclusion that orally administered PE is not effective as a nasal decongestant at the monographed dosage (10mg of PE hydrochloride every four hours), as well as at doses up to 40mg (dosed every four hours)."[22] Representative companies of the CHPA were present to argue the industry's point of view, which was ultimately rejected.[23]

76. In reaching that conclusion, "the Agency undertook a careful and thorough review of all the available data" and concluded that "[t]he new data appear compelling that the

[22] NDAC Briefing Document at 9

[23] The member companies of the CHPA that were present included at least certain defendants and others: Bayer, Perrigo, Kenvue, Sanofi, Lil' Drug Store, Foundation Consumer Healthcare, P&G, Reckitt and Haleon.

monographed dosage of oral PE results in no meaningful systemic exposure or evidence of efficacy."[24]

77. On September 11 and 12, 2023, the NDAC—a committee comprised of luminaries in the field of pharmacology—met to evaluate the new scientific evidence, as well as the old studies on efficacy.

78. Armed with the scientific consensus that had solidified by at least 2016 that phenylephrine is no more effective than a placebo, the committee unanimously agreed (16-0) that the scientific data do not support oral phenylephrine as an effective oral decongestant.

G. At Least One Defendant Issues A Weak Disclosure

79. Since the scientific consensus in 2016 that PE is no better than placebo, and even since the 16-0 vote by the NDAC recognizing that consensus, Defendants continued to produce, market, and sell PE Products without disclosing to consumers that the scientific consensus is (and has long been) that PE Products are ineffective.

80. ***Johnson & Johnson, however, through its actions, has admitted that it—and the other Defendants—could easily have made such a disclosure, and simply chose not to do so***.

81. Following the NDAC's advisory committee's findings, on its website for "Sudafed"—the brand through which Johnson & Johnson sells decongestants—Johnson & Johnson voluntarily added the following message next to the pictures of all of its phenylephrine-containing products:

> **In September, 2023, The Nonprescription Drugs Advisory Committee of the Food and Drug Administration reviewed efficacy data available for orally administered phenylephrine (PE) as a nasal decongestant. Read the FDA's statement about this review **here**.*[25]

[24] *Id*. at 14

[25] *See*, *e.g.*, https://www.sudafed.com/products/sudafed-pe-sinus-congestion?bvstate=pg:2/ct:r

82. The word "here" contains a hyperlink to a statement put out by the FDA following the September 11-12 NDAC meeting. In that statement, the FDA notes that the NDAC "discussed new data on the effectiveness of oral phenylephrine and concluded that the current scientific data *do not support* that the recommended dosage of orally administered phenylephrine is effective as a nasal decongestant."[26]

83. However, Johnson & Johnson continues to sell a number of PE Products. Indeed, on the very website where it now has a hyperlink to the FDA's "is not effective" statement, Johnson & Johnson expressly warrants that Sudafed PE provides "effective, non-drowsy symptom relief," even though it knows that Sudafed PE does no such thing.

84. Indeed, and as detailed below in Part V multiple Plaintiffs purchased those products, based on Johnson & Johnson's, and other Defendants', failure to disclose the true nature of phenylephrine, and their misleading and false representations that phenylephrine actually works as a decongestant when orally ingested.

H. Some Defendants Also Engaged in a Coordinated Effort to Defraud Consumers

85. The following factual allegations (i.e., Paragraphs 85-130) apply solely to Count 7 and are not alleged as to other counts.

86. As soon as the efficacy of PE Products was challenged, a core group of manufacturers associated together, including through a national trade association, the CHPA. The group included at least Defendants Bayer Healthcare LLC, Haleon PLC, Haleon U.S. Capital L.L.C., Haleon U.S. Holdings L.L.C., Perrigo Company, Proctor & Gamble Co., RB., Reckitt

[26] https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-results-recent-advisory-committee-meeting-oral-phenylephrine#:~:text=The%20committee%20discussed%20new%20data,effective%20as%20a%20nasal%20adecongestant

Benckiser L.L.C., Reckitt Benckiser Pharmaceuticals Inc., Kenvue, Inc., Johnson & Johnson (collectively, the "RICO Defendants").

87. From late 2006 to present, these manufacturers collectively worked in concert to track developments and share information about PE Products. For more than fifteen years, they worked in concert to aggressively represent to consumers and regulators that PE Products are effective. Each time a challenge was made to phenylephrine's effectiveness, or a new study showed that phenylephrine was not effective, this group responded with baseless and deceptive press releases and submissions designed to mislead consumers and misguide and delay the FDA's review process.

88. These efforts began in 2007, in response to the first Citizen's Petition, and continue to this day. Indeed, even after 2023 NDAC's unanimous vote, this group continues to assert in the press and to regulators that PE Products are effective. However, they have not identified a single new study from the past 40 years that demonstrates that PE is effective at decongesting. Nonetheless, to this day, this group continues to assert in the press and to regulators that PE Products are effective.

1. In 2006, The RICO Defendants Infiltrate the CHPA And Use The CHPA Phenylephrine Task Group As An Enterprise To Defraud The Public

89. Each RICO Defendant is a member of the CHPA, which was founded in 1881 and is a national trade association representing manufacturers and marketers of consumer healthcare products, including over-the-counter medications, dietary supplements, and medical devices.

90. By at least December 2006—*i.e.*, shortly following the move of pseudoephedrine "behind the counter"—the CHPA formed a Phenylephrine Task Group (the "Task Group"). On information and belief, each RICO Defendant is a member and/or participant in the Task Group.

91. Since its formation, the Task Group has continued to function as a unified organization and continuing unit for the common purpose of allowing the manufacturers and marketers of oral phenylephrine products to collaborate and regularly track developments related to phenylephrine's effectiveness. It accordingly has engaged in regular communications and actively monitored all developments related to oral phenylephrine from 2006 to the present day.[27]

92. In response to the February 2007 Citizen's Petition discussed above that questioned the efficacy of the 10mg dose of phenylephrine, the RICO Defendants—all of whom themselves were, or whose corporate predecessors were, members of CHPA—worked through the Task Group to respond.

93. Realizing how much revenue they collectively stood to lose if consumers were no longer buying over-the-counter PE Products, the RICO Defendants used the Task Group to represent to the FDA that they had come together to "critically assess all studies reviewed by the 1976 OTC expert advisory review panel and additional data on the efficacy and safety of phenylephrine in adults."[28] Toward this purported end, the Task Group, through CHPA, put together a "meta-analysis" that purported to analyze the early studies of phenylephrine's efficacy.

94. In truth, however, the RICO Defendants created a deliberately flawed meta-analysis, relying on old studies that the FDA would later characterize as suffering from "significant methodological and statistical issues, as well as potential data integrity issues"[29] to compete with a meta-analysis presented by the Citizens' Petition filed in February 2007. The Task Group did not "critically evaluate" the studies and data.

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[27] Although many of the specific activities of the CHPA Phenylephrine Task Group are shielded from public view and will not be known until discovery, publicly available information confirms that the group has been acting as a continuing unit for at least 17 years—*i.e.*, from 2006 to the present day.
[28] CHPA Briefing Book Submitted to NDAC, December 2007 [Docket No. 2007P-0047], at p. 2.
[29] NDAC Briefing Document at 54

95. For example, the Task Group did not evaluate the source of the studies or disclose that six of the seven studies purportedly supporting phenylephrine's efficacy came from the same sponsor (Sterling-Winthrop Research Institute on behalf of Winthrop Labs, the manufacturer of the phenylephrine product Neo-Synephrine) or that five of the studies were performed at a single laboratory, Elizabeth Biochemical. Years later, when FDA scientists and the NDAC critically evaluated all of the studies and data, as CHPA's Task Group claimed to have done in 2007, it found that these studies were deeply flawed. Indeed, and as explained in more detail below, a "critical analysis" of the Elizabeth Biochemical data would reveal that the data were likely infected by fraud—*i.e.*, doctored to support a finding of phenylephrine's effectiveness.

96. CHPA also stated in 2007: "The oral bioavailability of phenylephrine in adults is about 38% . . . ." [30] When the FDA and the advisory committee reviewed the early studies that supposedly supported this assertion, as well as new studies, FDA scientists determined that the old studies had serious design flaws and the new studies showed that the actual oral bioavailability of phenylephrine in adults is less than 1%.

97. In short, the RICO Defendants and the Task Group did not "critically assess" the studies or data that existed in 2007, but, instead, identified the studies that supported their position and then created a meta-analysis of only that data and those studies, without critically assessing the studies' design or reliability.

98. Based on the conflicting submissions, the NDAC did not recommend any major change in 2007. Instead, nine of the twelve panel members sitting in 2007 (the panel would later expand to 16 voting members in 2023) found that "due to the limitations of the data" available, it

[30] CHPA Briefing Book to NDCA, December 2007, at p. 3.

was recommended that "additional clinical data would be necessary, including new studies that should evaluate the decongestant effect of higher doses of oral PE."[31]

2. In Response To New Science, the RICO Defendants' CHPA Phenylephrine Task Group Misleads The Public

99. As discussed in detail above, certain manufacturers and several researchers performed and/or published multiple studies in the wake of the 2007 Citizen's Petition designed to assess phenylephrine's effectiveness.

100. All of the studies confirmed that oral phenylephrine is no better than placebo.

101. Between 2007 and 2015, the RICO Defendants used the Task Group to engage in a regular course of conduct as a continuing unit by monitoring new developments regarding the effectiveness of oral phenylephrine, maintaining communications as a group about any new publicly available information, and delegating tasks to different members related to the working group.

102. They knew in 2015 that new scientific evidence—including but not limited to the Horak, Day, and 2015 Melzer study described above—had emerged confirming that oral phenylephrine was not effective as a decongestant.

103. In 2015, a second Citizen's Petition was filed by Leslie Hendeles, PharmD, and Randy Hatton, PharmD, this time requesting that the FDA remove phenylephrine from the monograph for oral nasal decongestant products.[32]

104. The Task Group responded by attempting to mislead. They made their own submission to the FDA to compete with the Citizen's Petition. Instead of designing new studies of phenylephrine's efficacy, the RICO Defendants used the Task Group to coordinate and make

[31] NDAC Briefing Document at 30.
[32] Hendeles L, Hatton RA. Citizen Petition – Phenylephrine. Docket ID: FDA-2015-P-4131, available at: https://www.regulations.gov/docket/FDA-2015-P-4131.

baseless, misleading, and false assertions in a submission in 2016, to support the conclusion that "the Citizen's Petition does not provide sufficient scientific evidence to refute the established efficacy of phenylephrine at the 10 mg dose."[33]

105. For example, instead of objectively evaluating the science, in their own 2016 submission, the Task Group cherry-picked statements from the NDAC's 2007 meeting to assert falsely that the FDA's NDAC members concluded that the fourteen clinical studies assessed in 1976 "documented the effectiveness of phenylephrine hydrochloride as an oral nasal decongestant."[34] Of course, the NDAC in 2007 did no such thing, and had instead made clear that "additional clinical data would be necessary, including new studies that should evaluate the decongestant effect of higher doses of oral PE," using "subjective symptom scores rather than use objective measurement of NAR as the primary endpoint."[35] In other words, CHPA and the Task Group advanced the false narrative that the existing early studies already documented the effectiveness of oral phenylephrine.

106. Then, the Task Group raised what it called "significant concerns with design aspects and the interpretation of results in the [new] studies that were cited [in the 2015 Citizen's Petition]."[36] According to Task Group, "[n]one of the studies cited in the Citizen Petition is adequately designed to provide data that would reverse the previous determination regarding the efficacy of phenylephrine."[37]

107. Tellingly, even though the FDA's NDAC in 2007 had provided clear feedback that more clinical data was needed to make a final decision about the effectiveness of oral PE, the

[33] CHPA Submission to FDA [Docket FDA-2015-P-4131], April 21, 2016 at p. 1 ("CHPA 2016 FDA Submission")
[34] *Id.* at 3
[35] NDAC Briefing Document at 30.
[36] CHPA 2016 FDA Submission at 3.
[37] *Id.*

RICO Defendants and the Task Group did not identify any new studies initiated by CHPA or any of its members in the nine years since the NDAC meeting in 2007.

108. Trying to undermine the credibility of the new studies, the Task Group again represented that "Members of the CHPA Phenylephrine Task Group have critically evaluated the particular studies cited in the Citizen Petition relative to their merit in supporting the request that phenylephrine 10 mg be removed from the Final Monograph for OTC nasal decongestant products."[38] This representation implied that members of the Task Group were devoting resources and time to have scientists objectively evaluate these new studies and the studies' conclusions in an endeavor to find the truth.

109. The CHPA then pointed to what it called "serious study design issues" and identified statements by the authors in the new studies that were supposedly inaccurate or misleading.

110. For example, the Task Group accused the authors of the 2015 Meltzer study of implying that the study was done specifically at the request of the FDA.[39] The authors implied no such thing. The Task Group also falsely stated the study had "specific design elements" that "confound a generalized conclusion regarding the efficacy of phenylephrine."[40] However, no issue in the Meltzer study reasonably confounded the result.

111. The criticisms were baseless, in bad faith, and designed to imply that the authors were not being honest and the studies were fundamentally flawed. The Task Group made other baseless criticisms of the other studies cited in the Citizen's Petition, and ignored entirely other new studies—such as, *e.g.*, the Johnson & Johnson study described above—by the industry that

[38] *Id*.
[39] *Id*. at p. 4.
[40] Id. at p. 5.

concurred with the new studies in the Citizen's Petition and showed that oral phenylephrine is not effective.[41]

112. Through CHPA's baseless and deceptive assertions, instead of scientific consensus that should have existed by at least 2016, the American public and FDA were both again presented with conflicting presentations and mixed assertions about the efficacy of oral phenylephrine as a nasal decongestant.

113. The Task Group also issued press releases ignoring the new scientific evidence about phenylephrine's lack of effectiveness. For example, on May 4, 2017, CHPA's Task Group issued a press release about a study that had been undertaken regarding the safety of cough and cold medications for children—essentially, an analysis indicating that over-the-counter drugs like PE Products did not cause serious adverse events. The press release then announced:

> When OTC medicines are used as directed and labeled, **they provide the efficacy and safety that consumers demand,**" said Barbara Kochanowski, PhD, senior vice president for regulatory and scientific affairs at CHPA, the trade group that funded the study. "**This study should be reassuring to healthcare professionals who recommend OTC medicines, parents who use them, and retailers who sell them**. They each play a vital role in keeping children safe and healthy.[42]

114. Of course, by this time in 2017, new scientific evidence had established that oral phenylephrine over-the-counter nasal decongestants do not work for adults or children, and the study described by the press release had nothing to do with efficacy at all. Rather, the study collected evidence regarding serious adverse events associated with pediatric exposure to the OTC medication in response to a different Citizen's Petition. So, while the Task Group did not fund any studies that were published showing the efficacy of these PE Products in children or adults,

[41] Id. at p. 6-11.
[42] https://www.chpa.org/news/2017/05/study-shows-safety-cough-and-cold-medicines-children (emphasis added).

CHPA continued to tout the efficacy of phenylephrine and other OTC medications even though by 2016, the science was clear that the PE Products *have no efficacy*.

3. When the FDA Convenes the NDAC, the RICO Defendants Again Use the CHPA to Engage in Fraud

115. When the FDA announced that it was convening a meeting of the NDAC to discuss new data regarding the effectiveness of oral phenylephrine, the industry pushed for more time to respond. The FDA agreed. On March 21, 2023, the CHPA released a statement to the public[43]:

> CHPA is pleased to see today's news that FDA has postponed the recently announced Advisory Committee meeting," said Senior Vice President of Regulatory & Scientific Affairs, Barbara A. Kochanowski, Ph.D. "Given the critical importance of this meeting on behalf of the millions of consumers who rely on this ingredient, a reasonable amount of time is needed for regulated Industry to provide a complete picture of the previously reviewed data demonstrating phenylephrine as generally recognized as safe and effective (GRASE). It is imperative that the advisory committee has access to all the data in order to provide FDA the best possible advice as the Agency undertakes this evaluation.

116. Once again, the Task Group attempted to influence public opinion with misleading data. CHPA, on information and belief due to the influence of the RICO Defendants associating through the Task Group, conducted a consumer survey on phenylephrine between July 24-28, 2023. On August 3, 2023, CHPA developed what it called the "key findings" of the survey, which it published on its website.[44] According to CHPA, 83% of respondents stated that medicines with phenylephrine help relieve their nasal congestion, and 66% of the respondents stated that phenylephrine helps them get through their day because it relieves their nasal congestion. CHPA's findings summary concluded: "American adults repeatedly rely on oral PE because they recognize its efficacy as a nasal decongestant, they see the physical and personal benefits of oral PE when

[43] CHPA Press Release, March 21, 2023, available at: https://chpa.org/news/2023/03/chpa-statement-fda-postponing-april-12-ndac-meeting

[44] https://www.chpa.org/sites/default/files/media/docs/2023-08/PE%20Survey%20Results%20With%20Toplines%20FINAL%20%28web%29.pdf?_ga=2.142796469.1621163183.1714307947-754075134.1714307947

they use it, and they—and the overall healthcare system—would be significantly burdened if oral PE were not available OTC." On August 23, 2023, CHPA issued a press release touting the results of this consumer survey.[45]

117. Of course, consumers have insufficient scientific knowledge or access to clinical data to know whether phenylephrine products actually work. Moreover, many cold and allergy medicines sold by Defendants contain phenylephrine in combination with other active ingredients that actually do provide relief from other cold and allergy symptoms, just not nasal congestion. Instead of investing in robust clinical studies with scientific evidence, CHPA chose to spend its resources on a consumer survey showing, at best, that they had successfully duped the public in convincing them that the PE Products were effective decongestants. CHPA nevertheless spun the results of the consumer survey as though the consumer survey represented a scientific result regarding phenylephrine's effectiveness.

118. Armed with its new consumer survey, CHPA's Task Group, whose statements still purported to "reflect the collective views" of its member companies,[46] made a submission from the industry to the NDAC, asserting that the Task Group disagreed with the Citizen's Petition's claims that new data demonstrated PE is not an effective nasal decongestant. According to CHPA, the "efficacy and safety of PE has undergone multiple rigorous reviews undertaken by expert

[45] https://chpa.org/news/2023/08/study-consumers-use-trust-and-depend-otc-phenylephrine-pe-self-care-decongestion

[46] CHPA Briefing Book Submission to NDCA [Docket No. FDA-2023-N-2653], Sept. 11-12, 2023, at p. 7 fn.18 of 66 ("The information provided in this document reflects the collective views of the following CHPA member companies that currently market products containing phenylephrine: Bayer Consumer Health, Foundation Consumer Healthcare, LLC; Haleon (formerly GlaxoSmithKline Consumer Healthcare); Kenvue (formerly Johnson & Johnson Consumer, Inc.); Lil' Drug Store Products, Inc; Perrigo Company; Reckitt; Sanofi Consumer Healthcare; and the Procter & Gamble Company").

scientific bodies and FDA."[47] However, despite the NDAC's clear statement in 2007 that more clinical data regarding efficacy were needed, the RICO Defendants and the Task Group did not submit any new studies supporting its position, instead again doing no more than trying to undermine the new studies and defend antiquated studies from the 1950s, 1960s, and 1970s. CHPA's claim that phenylephrine's "efficacy and safety…has undergone multiple rigorous reviews"—and the implication that those reviews led to a conclusion that PE was efficacious—was a baseless statement made in bad faith.

119. As discussed above, when the FDA reviewed the new studies conducted since 2007, its scientists reached an "initial conclusion that orally administered PE is not effective as a nasal decongestant at the monographed dosage (10mg of PE hydrochloride every 4 hours) as well as at doses up to 40 mg (dosed every four hours)."[48] In reaching that conclusion, "the Agency undertook a careful and thorough review of all the available data" and concluded that "[t]he new data appear compelling that the monographed dosage of oral PE results in no meaningful systemic exposure or evidence of efficacy."[49]

120. As also discussed above, on September 11-12, 2023, the NDAC convened and reviewed all of the scientific information, including the new studies that the Task Group had tried to undermine in 2016 and beyond. The panel of experts voted unanimously (16-0) that phenylephrine is not effective. The FDA and the advisory committee relied on clinical data and studies that were all completed and published by 2018, paying particular attention to the Meltzer studies, both of which were published by January 2016.

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[47] CHPA Briefing Book Submission to NDCA [Docket No. FDA-2023-N-2653], Sept. 11-12, 2023, at p. 5 of 66; *See also* CHPA PPT Presentation to NDCA, Sept. 11-12, 2023, available at: https://www.fda.gov/media/171972/download.
[48] NDAC 2023 Briefing Document at 9
[49] *Id.* at 14.

121. The RICO Defendants and CHPA did not identify a single clinical study conducted by CHPA or any of its members after 2007 that supported the efficacy of oral phenylephrine as a nasal decongestant.

122. On September 7, 2023, shortly before the NDAC convened, the CHPA, on information and belief due to the influence of the RICO Defendants/Task Group, issued a press release.[50] This press release contained numerous misleading statements attempting to convince the American public and NDAC that oral phenylephrine was effective, despite CHPA's and Defendants' knowledge since 2016 that the scientific evidence had proven oral phenylephrine is no better than placebo. The misleading nature of the statements in the press release are described herein:

CHPA Phenylephrine Task Group Statement	**Why Misleading[51]**
"Oral phenylephrine (PE) has been relied upon as a beneficial nasal decongestant by American families for decades, and FDA has repeatedly concluded the ingredient is safe and effective. This determination, established by multiple double-blind, placebo-controlled trials and supported by two previous FDA advisory panels, has also been validated by a meta-analysis of relevant clinical studies."	All of these trials were conducted over 40 years ago, and the FDA advisory panel requested more clinical data in 2007, specifically finding that the old data did not sufficiently support efficacy of PE. CHPA's Task Group did not submit or rely on any new clinical data since 2007, despite the NDAC request for more clinical data. The old studies from the 1950s, 1960s and 1970s had obvious design flaws and were highly questionable, as explained below, which would have been evident had CHPA's Task Group critically assessed these studies, as it claimed to have done in 2007.
"When it comes to consumers' needs, a recent national survey revealed that American	The Task Group's consumer studies show not that the products work but that

[50] https://www.chpa.org/news/2023/09/statement-sept-11-12-2023-meeting-fda-ndac-evaluate-efficacy-oral-pe

[51] The press release relies on this series of half-truths—deceptive statements that include some element of truth but conceals important material information from the reader.

adults repeatedly rely on oral PE because they recognize its benefits when they use it. In fact, 83% of consumers who used a product containing PE in the past year agreed the medicines helped relieve their nasal or sinus congestion. Respondents also reported PE further relieves their symptoms and overall ability to sleep, work, and get through their day."	these products are a placebo and American consumers were misled into buying products that do not work because they believed they did work. No rational consumer would buy a product that science shows does not work.
"As scientific techniques and methodologies progress, it is important to integrate new data within the broader framework of existing evidence rather than viewing it as a complete substitute for the previous body of evidence, particularly when assessing a well-established and globally used ingredient like PE for its safety and efficacy."	CHPA's Task Group did not provide any new data, the old data were not a body of evidence, and it was never well-established that oral phenylephrine was effective. In spite of the statement about integration of new data into existing scientific knowledge, the Task Group attempted at every turn to deny and discredit more recent and rigorous studies.

123. After the NDAC voted unanimously that phenylephrine is not effective, CHPA's Phenylephrine Task Group issued another press release to the public on September 12, 2023.[52] This press release also contains numerous misleading statements attempting to convince the American public to keep buying and taking oral phenylephrine as a nasal decongestant.

CHPA Phenylephrine Task Group Statement	**Why Misleading[53]**
"The regulations for phenylephrine (PE) remain unchanged, and there is no change in the availability of products containing PE on store shelves. The NDAC vote was a non-binding suggestion for the FDA to consider. Consumers can maintain their confidence in the fact that these medicines continue to be recognized as safe and effective by FDA."	This statement implies that consumers should continue to buy oral phenylephrine products because they work. However, the FDA scientists tasked with briefing the NDAC reached an initial conclusion that oral phenylephrine is not effective.

[52] https://www.chpa.org/news/2023/09/statement-following-september-2023-meeting-nonprescription-drugs-advisory-committee

[53] The press release relies on this series of half-truths—deceptive statements that include some element of truth but conceals important material information from the reader.

"We are disappointed by the outcome of today's FDA Advisory Committee meeting because its non-binding recommendation is at odds with the numerous clinical trials and previous regulatory determinations affirming oral PE as a safe and effective decongestant at its labeled dose," said CHPA President and CEO Scott Melville.	This statement implies that there are numerous clinical trials showing that phenylephrine is effective, but the FDA had already established that these trials had serious design flaws and this clinical data should not be relied upon.
"While we respect the scientific and public process that allows new science to influence health policy and regulations, we are concerned about previous clinical evidence being inappropriately dismissed and discounted."	All of the previous evidence is over 40 years old and, as the FDA scientists who analyzed phenylephrine's efficacy to brief the NDAC concluded, highly flawed.

124. What CHPA also did not mention in these press releases is that the "clinical trials" that all were submitted over 40 years ago (conducted at various times in the 1950s, 1960s, and 1970s) relied on science that has since been widely understood to be suspect. As the NDAC briefing document explains regarding those studies:

> When considering the studies through a modern drug review lens, all of the studies (both positive and negative) were highly problematic in both design and methodology. All used a highly variable endpoint (NAR) to study a drug in the setting of a highly variable disease state (the common cold) that is no longer used as a primary endpoint to evaluate congestion in pivotal trials. Further, all the positive studies (and most of the negative studies) were unpublished and therefore never peer reviewed. Six of the seven positive studies came from a single study center (funded by the manufacturer of Neo-Synephrine), were very small in size, and (except in one instance) the results could not be duplicated at two other study centers (also funded by the same manufacturer) that used a similar study design and methodology.
>
> Additionally, the positive oral PE results do not match what was demonstrated in multiple studies reviewed by the Panel that the dose of orally administered PE that is required to result in clinically relevant systemic (pharmacodynamic) effect is far higher than the monographed dose. Nor do they match what is now known about the bioavailability and PK of orally administered PE. As a result, and in retrospect, we believe that newer data and improvement in study methodologies suggest that the findings of the Panel should be revisited.
>
> And, in fact, we believe that the multiple methodological and statistical issues inherent in the studies reviewed by the Panel make the original studies evaluated

> for efficacy unacceptable as continued support for the efficacy of monographed doses of oral PE.[54]

125. Further, the NDAC Briefing document, prepared by FDA scientists, explains that the lab used in five of the seven early studies that purportedly supported phenylephrine's efficacy may have engaged in fraud. These studies took place in Elizabeth Biochemical Labs. As the FDA reviewers explained, the data produced by the Elizabeth Biochemical Labs were "textbook perfect results that could not be duplicated in other similarly designed studies that used the same methodology but were conducted at two other centers by the same sponsor."[55] They explained:

> Given the small sample size and the variability of the methodology and subject population, as well as the results of studies that have been reported since that time…the…results at the Elizabeth site can only be interpreted in one of two ways. Either the results reflect excellent study management that could not be duplicated at the other two sites, which does not make scientific sense based on the [pharmacokinetic] and [pharmacodynamic] data and the known variability in the methodology, or they reflect data that are simply too good to be real. As a result, the issue of bias and possible data integrity issues at the Elizabeth site must be seriously entertained.[56]

126. The CHPA did not mention any of this in its statement. It did not acknowledge that, since the suspect early studies, not a single study has found that oral phenylephrine is effective. It did not acknowledge that the new studies had, in fact, all proven the opposite, including decisive studies sponsored by industry members themselves, including the 2015 Meltzer study, the 2016 Meltzer study, and the 2017-18 Johnson & Johnson study.

127. Instead, the CHPA emphasized that "there is no change in the availability of products containing PE on store shelves."

128. As explained above, the RICO Defendants continued to sell their PE Products, and persisted in doing so even since 2016, when the science was crystal clear that oral phenylephrine

[54] NDAC Briefing Document at 54-55
[55] NDAC Briefing Document at 32.
[56] *Id*. at 62

is no more effective than placebo at decongesting. Each package and label of oral phenylephrine products sold by the RICO Defendants contains false and misleading statements, as explained above, and materially omitted the truth about phenylephrine's efficacy.

129. The RICO Defendants were only able to continue selling these products to American consumers because they used the CHPA Phenylephrine Task Group as a vehicle to further and conceal their scheme to defraud American consumers, undermine new scientific evidence showing oral phenylephrine is not effective, and substantially delay the FDA's review process.

130. In short, the RICO Defendants came together through CHPA to conduct the affairs of an Enterprise; they conducted the Enterprise's affairs through a pattern of racketeering activity, including by using the Enterprise to perpetrate a fraud and conceal the true nature of their PE Products; and Plaintiffs and the other Class members suffered economic injury "by reason of" the pattern of racketeering activity.

V. DEFENDANTS MISLED PLAINTIFFS

Sandra Yousefzadeh

131. Plaintiff Sandra Yousefzadeh ("Yousefzadeh") is a citizen of the State of New York who resides in the incorporated village of Kings Point.

132. Yousefzadeh suffers from seasonal allergies and post-nasal drip. These conditions cause her to experience frequent symptoms such as nasal and/or sinus congestion, coughing, and headaches. On numerous occasions she has taken over-the-counter oral decongestants in order to obtain relief from these symptoms.

133. On August 23, 2023, Yousefzadeh purchased two packages of 24 tablets of Sudafed PE® Sinus Pressure + Pain Maximum Strength, a product manufactured and/or labeled by Johnson & Johnson, from Amazon.com Services LLC ("Amazon"), for $6.97 per package.

134. Yousefzadeh made this purchase because she wanted medication that contained an active ingredient that would be effective in treating her nasal and/or sinus congestion.

135. Yousefzadeh purchased the "Maximum Strength" version of the decongestant because she wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating her nasal and/or sinus congestion.

136. In making her purchase, Yousefzadeh relied upon the product packaging and the "Sudafed" brand name to make her purchasing decision—she read on the photos of the packaging on the Amazon website that the product was "Maximum Strength" and promised to relieve "Sinus Pressure + Congestion" and "Sinus Headache." In addition, Yousefzadeh knew from seeing years of advertising that "Sudafed" was a brand name for over-the-counter drugs effective at relieving congestion. She trusted that any product named "Sudafed" would be an effective decongestant.

137. In making her purchase, Yousefzadeh was also misled by Johnson & Johnson's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Yousafzadeh would not have purchased this PE Product had Johnson & Johnson informed her of its lack of efficacy in relieving congestion or she would have paid significantly less than she paid insofar as this PE Product was only effective in treating her other symptoms and was not effective in treating sinus pressure and congestion.

138. Upon learning from an acquaintance that an FDA Advisory Panel had determined that the active ingredient in Sudafed PE was ineffective as an oral decongestant, Yousefzadeh retained counsel to protect her rights.

139. On September 14, 2023, Yousefzadeh caused a Notice of Breach to be sent via FedEx Corporation to Johnson & Johnson, advising that they had breached the express and implied warranties they had made to her when she purchased Sudafed PE® Sinus Pressure + Pain Maximum Strength because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

Anntwanette Jones

140. Plaintiff Anntwanette Jones ("Jones") is a citizen of the State of New York who resides in the City of Buffalo.

141. From time to time, Jones catches the common cold or seasonal flu. When she catches a cold or flu, she experiences symptoms such as nasal and/or sinus congestion. She takes multiple over-the-counter oral decongestants for relief from these symptoms that she has purchased from Walmart and Target in Buffalo.

(a) Jones Purchased Vicks® Dayquil™ SEVERE Honey Cold & Flu

142. Within the last three years, Jones has purchased in New York at least one package of "Vicks® Dayquil™ SEVERE Honey Cold & Flu", a product manufactured and/or labeled by P&G.

143. Jones made this purchase because she wanted medication that contained an active ingredient that would be effective in treating her nasal and/or sinus congestion.

144. Jones purchased the "Severe" version of the decongestant because she thought her symptoms were or would be "severe," and she wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating her nasal and/or sinus congestion.

145. In making her purchase, Jones relied upon the product packaging and the "Vicks," and "DayQuil" brand names to make her purchasing decision—she read on the package that the product was for "Severe Cold & Flue," and that it promised to relieve "Nasal Congestion" and "Sinus Pressure." Further, Jones knew from seeing years of advertising that "Vicks" and "DayQuil" were brand-names for over-the-counter decongestants. She trusted that any product bearing the "Vicks," and "DayQuil" brand names would be an effective decongestant.

146. In making her purchase, Jones was also misled by P&G's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Jones would not have purchased this PE Product had P&G informed her of its lack of efficacy in relieving congestion or she would have paid significantly less than she paid insofar as this PE Product was only effective in treating her other symptoms and was not effective in treating sinus pressure and congestion.

147. Upon learning from her attorneys in prior litigation that an FDA Advisory Panel had determined that an that an active ingredient in Vicks® Dayquil™ SEVERE Honey Cold & Flu was ineffective as an oral decongestant, Jones retained counsel to protect her rights.

148. On April 25, 2024, Jones caused a Notice of Breach to be sent via U.S. Mail to P&G, advising that they had breached the express and implied warranties they had made to her when she purchased Vicks® Dayquil™ SEVERE Honey Cold & Flu because "the active nasal

decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(b) Jones Purchased Equate Children's Multi-Symptom Cold Liquid, Very Berry

149. Jones is the mother of a daughter who is currently ten years old.

150. From time to time, Jones's daughter catches the common cold or seasonal flu. When Jones's daughter catches a cold or flu, she experiences symptoms such as nasal and/or sinus congestion. Jones gives her daughter over-the-counter oral decongestants for children for relief from these symptoms that Jones has purchased from Walmart and Target in Buffalo.

151. Within the last three years, Jones has purchased in New York at least one package of "Equate Children's Multi-Symptom Cold Liquid, Very Berry, 4 fl oz," a product manufactured and/or labeled by Walmart.

152. Jones made this purchase because she wanted medication that contained an active ingredient that would be effective in treating her daughter's nasal and/or sinus congestion.

153. In making her purchase, Jones relied upon the product packaging and the "equate" brand name to make her purchasing decision—she read on the package that the product promised to relieve "stuffy nose." She trusted that any product bearing Walmart's "equate" brand name would be an effective decongestant.

154. In making her purchase, Jones was also misled by Walmart's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Jones would not have purchased this PE Product had Walmart informed her of its lack of efficacy in relieving congestion or she would have

paid significantly less than she paid insofar as this PE Product was only effective in treating her daughter's other symptoms and was not effective in treating sinus pressure and congestion.

155. Upon learning from her attorneys in prior litigation that an FDA Advisory Panel had determined that an active ingredient in Equate Children's Multi-Symptom Cold Liquid, Very Berry was ineffective as an oral decongestant, Jones retained counsel to protect her rights.

156. On April 25, 2024, Jones caused a Notice of Breach to be sent via U.S. Mail to Walmart advising that they had breached the express and implied warranties they had made to her when she purchased Equate Children's Multi-Symptom Cold Liquid, Very Berry because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(c) Jones Purchased Delsym® Children's Cough+ Cold Nighttime Berry Flavored Liquid

157. Within the last three years, Jones has purchased in New York at least one package of "Delsym® Children's Cough+ Cold Nighttime Berry Flavored Liquid," a product manufactured and/or labeled by RB.

158. Jones made this purchase because she wanted medication that contained an active ingredient that would be effective in treating her daughter's nasal and/or sinus congestion.

159. In making her purchase, Jones relied upon the product packaging and the "Delsym" brand name to make her purchasing decision—she read on the package that the product promised to relieve "stuffy nose." She trusted that any product bearing the "Delsym" brand name would be an effective decongestant.

160. In making her purchase, Jones was also misled by RB's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at

decongesting than placebo when taken orally. Jones would not have purchased this PE Product had RB informed her of its lack of efficacy in relieving congestion or she would have paid significantly less than she paid insofar as this PE Product was only effective in treating her daughter's other symptoms and was not effective in treating sinus pressure and congestion.

161. Upon learning from her attorneys in prior litigation that an FDA Advisory Panel had determined that an active ingredient in Delsym® Children's Cough+ Cold Nighttime Berry Flavored Liquid was ineffective as an oral decongestant, Jones retained counsel to protect her rights.

162. On April 25, 2024, Jones caused a Notice of Breach to be sent via U.S. Mail to RB Health (US) LLC advising that they had breached the express and implied warranties they had made to her when she purchased Delsym® Children's Cough+ Cold Nighttime Berry Flavored Liquid because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

Daniel Calzado

163. Plaintiff Daniel Calzado ("Calzado") is a citizen of the State of New York who resides in the City of Rochester.

164. From time to time, Calzado catches the common cold or seasonal flu. When he catches a cold or flu, he experiences symptoms such as nasal and/or sinus congestion. He takes over-the-counter oral decongestants for relief from these symptoms.

(a) Calzado Purchased Vicks NyQuil™ SEVERE Maximum Strength Cold & Flu Berry Flavored Liquid Medicine

165. On or about November 2023, Calzado purchased one package of 12 fluid ounces of "Vicks NyQuil™ SEVERE Maximum Strength Cold & Flu Berry Flavored Liquid Medicine," a

product manufactured and/or labeled by P&G, from CVS Pharmacy, 525 Spencerport Road Shopping Paza, Rochester, New York.

166. Calzado made this purchase because he wanted medication that contained an active ingredient that would be effective in treating his nasal and/or sinus congestion.

167. Calzado purchased the "Maximum Strength" version of the decongestant because he wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating his nasal and/or sinus congestion.

168. In making his purchase, Calzado relied upon the product packaging and the "NyQuil" brand name to make his purchasing decision—he read on the package that the product was "Maximum Strength" and that it promised to relieve "Nasal Congestion, Sinus Pressure." Further, Calzado knew from seeing years of advertising that "NyQuil" was a brand-name for over-the-counter decongestants. He trusted that any product named "NyQuil" would be an effective decongestant.

169. In making his purchase, Calzado was also misled by P&G's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally Calzado would not have purchased this PE Product had P&G informed him of its actual lack of efficacy in relieving congestion or he would have paid significantly less than he paid insofar as this PE Product was only effective in treating his other symptoms and was not effective in treating sinus pressure and congestion.

170. Upon learning from his attorneys in prior litigation that an FDA Advisory Panel had determined that the active ingredient in Vicks NyQuil was ineffective as an oral decongestant, Calzado retained counsel to protect his rights.

171. On April 25, 2024, Calzado caused a Notice of Breach to be sent via U.S. Mail to P&G, advising that they had breached the express and implied warranties they had made to him when he purchased Vicks NyQuil™ SEVERE Maximum Strength Cold & Flu Berry Flavored Liquid Medicine because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(b) Calzado Purchased CVS Health Non-Drowsy Nasal Decongestant PE Maximum Strength

172. Within the applicable class period, Calzado purchased at least one package of "CVS Health Non-Drowsy Nasal Decongestant PE Maximum Strength" from a CVS in Rochester, NY.

173. Calzado made this purchase because he wanted medication that contained an active ingredient that would be effective in treating his nasal and/or sinus congestion.

174. Calzado purchased the "Maximum Strength" version of the product because he wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating his nasal and/or sinus congestion.

175. In making his purchase, Calzado relied upon the product packaging and the "CVS Health" brand name to make his purchasing decision—he read on the package that the product was "Maximum Strength" and that it promised to relieve "Nasal Congestion, Sinus Pressure." In addition, Calzado knew from seeing years of advertising that "CVS Health" was a brand-name for over-the-counter decongestants. He trusted that any decongestant product named "CVS Health" would be an effective decongestant. In making his purchase, Calzado was also misled by CVS's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product,

phenylephrine, is no more effective at decongesting than placebo when taken orally. Calzado would not have purchased this PE Product had CVS informed him of its lack of efficacy in relieving congestion or he would have paid significantly less than he paid insofar as this PE Product was only effective in treating his other symptoms and was not effective in treating sinus pressure and congestion.

176. Upon learning from his attorneys in prior litigation that an FDA Advisory Panel had determined that the active ingredient in CVS Health Non-Drowsy Nasal Decongestant PE Maximum Strength was ineffective as an oral decongestant, Calzado retained counsel to protect his rights.

177. On May 3, 2024, Calzado caused a Notice of Breach to be sent via U.S. Mail to CVS Corporation advising that they had breached the express and implied warranties they had made to him when he purchased CVS Health Non-Drowsy Nasal Decongestant PE Maximum Strength because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(c) Calzado Purchased CVS Health Non-Drowsy Sinus PE Pressure, Pain + Cold

178. Within the applicable class period, Calzado purchased at least one package of "CVS Health Non-Drowsy Sinus PE Pressure, Pain + Cold" from a CVS in Rochester, NY.

179. Calzado made this purchase because he wanted medication that contained an active ingredient that would be effective in treating his nasal and/or sinus congestion.

180. Calzado purchased this CVS Health Non-Drowsy Sinus PE Pressure, Pain + Cold decongestant product because he wanted to take a product with an active ingredient that would be effective in treating his nasal and/or sinus congestion.

181. In making his purchase, Calzado relied upon the product packaging and the "CVS Health" brand name to make his purchasing decision—he read on the package that the product promised to relieve "Nasal Congestion" and "Sinus congestion & Pressure." In addition, Calzado knew from seeing years of advertising that "CVS Health" was a brand-name for over-the-counter decongestants. He trusted that any decongestant product named "CVS Health" would be an effective decongestant. In making his purchase, Calzado was also misled by CVS's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Calzado would not have purchased this PE Product had CVS informed him of its lack of efficacy in relieving congestion or he would have paid significantly less than he paid insofar as this PE Product was only effective in treating his other symptoms and was not effective in treating sinus pressure and congestion.

182. Upon learning from his attorneys in prior litigation that an FDA Advisory Panel had determined that the active ingredient in CVS Health Non-Drowsy Sinus PE Pressure, Pain + Cold was ineffective as an oral decongestant, Calzado retained counsel to protect his rights.

183. On May 3, 2024, Calzado caused a Notice of Breach to be sent via U.S. Mail to CVS Corporation advising that they had breached the express and implied warranties they had made to him when he purchased CVS Health Non-Drowsy Sinus PE Pressure, Pain + Cold because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(d) Calzado Purchased Advil Multi-Symptom Cold & Flu

184. Within the applicable class period, Calzado purchased at least one package of "Advil Multi-Symptom Cold & Flu" from CVS in Rochester, NY.

185. Calzado made this purchase because he wanted medication that contained an active ingredient that would be effective in treating his nasal and/or sinus congestion.

186. Calzado purchased this Advil Multi-Symptom Cold & Flu decongestant product because he wanted to take a product with an active ingredient that would be effective in treating his nasal and/or sinus congestion.

187. In making his purchase, Calzado relied upon the product packaging and the "Advil" brand name to make his purchasing decision—he read on the package that the product promised to relieve "Nasal Congestion" and "Sinus Pressure." In addition, Calzado knew from seeing years of advertising that "Advil" was a brand-name for over-the-counter decongestants. He trusted that any decongestant product named "Advil"" would be an effective decongestant. In making his purchase, Calzado was also misled by the Haleon's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Calzado would not have purchased this PE Product had Haleon informed him of its lack of efficacy in relieving congestion or he would have paid significantly less than he paid insofar as this PE Product was only effective in treating his other symptoms and was not effective in treating sinus pressure and congestion.

188. Upon learning from his attorneys in prior litigation that an FDA Advisory Panel had determined that the active ingredient in Advil Multi-Symptom Cold & Flu was ineffective as an oral decongestant, Calzado retained counsel to protect his rights.

189. On May 3, 2024, Calzado caused a Notice of Breach to be sent via U.S. Mail to CVS Corporation advising that they had breached the express and implied warranties they had made to him when he purchased Advil Multi-Symptom Cold & Flu because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

Eli Erlick

190. Plaintiff Eli Erlick ("Erlick") is a citizen of the State, City, and County of New York.

191. Erlick has contracted COVID-19 multiple times and also occasionally contracts the common cold and/or seasonal flu. These conditions cause her to experience symptoms including nasal and/or sinus congestion. She takes over-the-counter oral decongestants in order to seek relief from these symptoms and has been doing so for decades.

(a) Erlick Purchased Acetaminophen Day/Night Time Vapor Ice Cold and Flu Relief Caplets - 24ct - up & up™

192. On March 22, 2203, Erlick purchased Acetaminophen Day/Night Time Vapor Ice Cold and Flu Relief Caplets - 24ct - up & up™ medicine from Target in the state of New York.

193. Erlick made this purchase because she wanted medication that contained an active ingredient that would be effective in treating her nasal and/or sinus congestion.

194. Erlick purchased the "MAX Strength" version of the decongestant because she wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating her nasal and/or sinus congestion.

195. In making her purchase, Erlick relied upon the product to make her purchasing decision—she read on the packaging that the product was "MAX Strength" and that it promised

to relieve "nasal congestion and sinus pressure." She trusted that the product would be an effective decongestant.

196. In making her purchase, Erlick was also misled by Target's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Erlick would not have purchased this PE Product had Target informed her of its lack of efficacy in relieving congestion or she would have paid significantly less than she paid insofar as this PE Product was only effective in treating her other symptoms and was not effective in treating sinus pressure and congestion.

197. Upon learning that an FDA Advisory Panel had determined that the active ingredient in Acetaminophen Day/Night Time Vapor Ice Cold and Flu Relief Caplets - 24ct - up & up was ineffective as an oral decongestant, Erlick retained counsel to protect her rights.

198. On May 2, 2024 Erlick caused a Notice of Breach to be sent via U.S. Mail to Target Brands, Inc., advising that they had breached the express and implied warranties they had made to her when she purchased Acetaminophen Day/Night Time Vapor Ice Cold and Flu Relief Caplets - 24ct - up & up medicine because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(b) Erlick Purchased TYLENOL® Cold + Flu Severe For Day And Night

199. On March 22, 2023, Erlick purchased TYLENOL® Cold + Flu Severe For Day and Night caplets medicine, a product manufactured and/or labeled by Johnson & Johnson, from Amazon.com in the State of New York.

200. Erlick made this purchase because she wanted medication that contained an active ingredient that would be effective in treating her nasal and/or sinus congestion.

201. Erlick purchased the "Severe" version of the decongestant because she thought her symptoms were or would be "severe," and she wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating her nasal and/or sinus congestion.

202. In making her purchase, Erlick relied upon the photographs of the product packaging on the Amazon website to make her purchasing decision—she read on the packaging that the product was for "Severe Cold + Flu" and that it promised to relieve "Nasal Congestion." She trusted that the product would be an effective decongestant Further, Erlick knew from seeing years of advertising that "TYLENOL® Cold + Flu" was a brand name for over-the-counter decongestants. She trusted that any product bearing the "TYLENOL® Cold + Flu" brand name would be an effective decongestant.

203. In making her purchase, Erlick was also misled by Johnson & Johnson's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Erlick would not have purchased this PE Product had Johnson & Johnson informed her of its lack of efficacy in relieving congestion or she would have paid significantly less than she paid insofar as this PE Product was only effective in treating her other symptoms and was not effective in treating sinus pressure and congestion.

204. Upon learning that an FDA Advisory Panel had determined that the active ingredient in TYLENOL® Cold + Flu Severe For Day and Night that purported to decongest was ineffective as an oral decongestant, Erlick retained counsel to protect her rights.

205. On May 2, 2024, Erlick caused a Notice of Breach to be sent via U.S. Mail to Johnson & Johnson., advising that they had breached the express and implied warranties they had made to her when she purchased TYLENOL® Cold + Flu Severe For Day and Night medicine because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(c) Erlick Purchased Vicks NyQuil Severe Cold & Flu, 24 Liquicaps, Maximum Strength

206. On November 17, 2021, Erlick purchased Vicks NyQuil Severe Cold & Flu, 24 Liquicaps, Maximum Strength medicine, a product manufactured and/or labeled by P&G, from Amazon.com in the State of New York.

207. Erlick made this purchase because she wanted medication that contained an active ingredient that would be effective in treating her nasal and/or sinus congestion.

208. Erlick purchased the "SEVERE" version of the decongestant because she thought her symptoms were or would be "severe," and she wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating her nasal and/or sinus congestion.

209. Erlich purchased the "Maximum Strength" version of the decongestant because she wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating his nasal and/or sinus congestion.

210. In making her purchase, Erlick relied upon the photographs of the product packaging on the Amazon website to make her purchasing decision—she read on the packaging that the product was for "SEVERE" "Cold & Flu" and was "MAX Strength" and that it promised to relieve "Nasal Congestion" and "Sinus Pressure" She trusted that the product would be an effective decongestant. Further, Erlick knew from seeing years of advertising that "Vicks" and

NyQuil" were brand-names for over-the-counter decongestants. She trusted that any product bearing the "Vicks," "DayQuil," and "NyQuil" brand names would be an effective decongestant.

211. In making her purchase, Erlick was also misled by P&G's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Erlick would not have purchased this PE Product had P&G informed her of its lack of efficacy in relieving congestion or she would have paid significantly less than she paid insofar as this PE Product was only effective in treating her other symptoms and was not effective in treating sinus pressure and congestion.

212. Upon learning that an FDA Advisory Panel had determined that the active ingredient in Vicks NyQuil Severe Cold & Flu, 24 Liquicaps, Maximum Strength was ineffective as an oral decongestant, Erlick retained counsel to protect her rights.

213. On May 2, 2024, Erlick caused a Notice of Breach to be sent via U.S. Mail to P&G, advising that they had breached the express and implied warranties they had made to her when she purchased Vicks NyQuil Severe Cold & Flu, 24 Liquicaps, Maximum Strength medicine because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

John Sloughter

214. Plaintiff John Sloughter ("Sloughter") is a citizen of the State of New York who resides in the Town of Richford.

215. Sloughter occasionally contracts the common cold and/or seasonal flu and suffers from seasonal allergies. These conditions cause him to experience symptoms such as nasal and/or

sinus congestion. He takes over-the-counter oral decongestants for relief from these symptoms and has been doing so for decades.

216. In the last three years, Sloughter purchased Vicks DayQuil SEVERE Honey Flavored Maximum Strength Cold & Flu Liquid medicine, a product manufactured and/or labeled by P&G, in Ithaca, New York.

217. Sloughter made this purchase because he wanted medication that contained an active ingredient that would be effective in treating his nasal and/or sinus congestion.

218. Sloughter purchased the "Maximum Strength" version of the decongestant because he wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating his nasal and/or sinus congestion.

219. In making his purchase, Sloughter relied upon the product packaging and the "Vicks" and "DayQuil brand names to make his purchasing decision—he read on the packaging that the product was "Maximum Strength" and that it promised to relieve "Nasal Congestion, Sinus Pressure." Further, Sloughter knew from seeing years of advertising that "Vicks" and "DayQuil" were brand names for over-the-counter decongestants. He trusted that any product branded "Vicks" or "DayQuil" would be an effective decongestant.

220. In making his purchase, Sloughter was also misled by P&G's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Sloughter would not have purchased this PE Product had P&G informed him of its lack of efficacy in relieving congestion or he would have paid significantly less than he paid insofar as this PE Product was only effective in treating his other symptoms and was not effective in treating sinus pressure and congestion.

221. Upon learning that an FDA Advisory Panel had determined that the active ingredient in Sudafed PE was ineffective as an oral decongestant, Sloughter retained counsel to protect his rights.

222. On April 22, 2024, Sloughter caused a Notice of Breach to be sent via U.S. Mail to P&G, advising that they had breached the express and implied warranties they had made to him when he purchased Vicks DayQuil SEVERE Honey Flavored Maximum Strength Cold & Flu Liquid medicine because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

Keith Mortuiccio

223. Plaintiff Keith Mortuiccio ("Mortuiccio") is a citizen of the State of New York who resides in the City of Batavia.

224. Mortuiccio is a former member of the United States Armed Forces, who has been diagnosed by the Veterans Health Administration as suffering from respiratory conditions related to Burn Pit Exposure. As a result of these conditions, he suffers from, among other symptoms, nasal and/or sinus congestion. He has purchased multiple over-the-counter oral decongestants in order to seek relief from these symptoms from Walmart, Tops, Wegmans, and Walgreens near Batavia.

(a) Mortuiccio Purchased Mucinex Maximum Strength Sinus-Max® Day & Night

225. In the last three years, Mortuiccio has purchased in New York at least one package of 24 tablets of "Mucinex Maximum Strength Sinus-Max® Day & Night" liquid gels, a product manufactured and/or labeled by RB.

226. Mortuiccio made this purchase because he wanted medication that contained an active ingredient that would be effective in treating his nasal and/or sinus congestion.

227. Mortuiccio purchased the "Maximum Strength" version of the decongestant because he wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating his nasal and/or sinus congestion.

228. In making his purchase, Mortuiccio relied upon the product packaging and the "Mucinex" brand name to make his purchasing decision—he read on the package that the product was "Maximum Strength" and that it promised to relieve "Sinus Pressure, Headache & Congestion," as well as "Nasal Congestion, Sinus Pressure & Pain." In addition, Mortuiccio knew from seeing years of advertising that "Mucinex" was a brand-name for over-the-counter decongestants. He trusted that any product branded "Mucinex" would be an effective decongestant.

229. In making his purchase, Mortuiccio was also misled by RB's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Mortuiccio would not have purchased this PE Product had RB informed him of its lack of efficacy in relieving congestion or he would have paid significantly less than he paid insofar as this PE Product was only effective in treating his other symptoms and was not effective in treating sinus pressure and congestion.

230. Upon learning from his attorneys in prior litigation that an FDA Advisory Panel had determined that an active ingredient in Mucinex Sinus-Max was ineffective as an oral decongestant, Mortuiccio retained counsel to protect her rights.

231. On April 25, 2024, Mortuiccio caused a Notice of Breach to be sent via U.S. Mail to RB, advising that they had breached the express and implied warranties they had made to him when he purchased Mucinex Maximum Strength Sinus-Max® Day & Night because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(b) Mortuiccio Purchased TYLENOL® Cold + Flu Severe

232. In the last three years, Mortuiccio has purchased at least one package in New York of 24 caplets of TYLENOL® Cold + Flu Severe," a product manufactured and/or labeled by Johnson & Johnson.

233. Mortuiccio made this purchase because he wanted medication that contained an active ingredient that would be effective in treating his nasal and/or sinus congestion.

234. Mortuiccio purchased the "Severe" version of the decongestant because he thought his symptoms were or would be "severe," and he wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating his nasal and/or sinus congestion.

235. In making his purchase, Mortuiccio relied upon the product packaging and the "TYLENOL®" brand name to make his purchasing decision—he read on the package that the product was for "Severe" "Cold + Flu" and that it promised to relieve "Nasal Congestion." Further, Mortuiccio knew from seeing years of advertising that "TYLENOL®" was a brand-name for over-the-counter medications. He trusted that any product bearing the "TYLENOL®" brand name would be an effective decongestant.

236. In making his purchase, Mortuiccio was also misled by Johnson & Johnson's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product,

phenylephrine, is no more effective at decongesting than placebo when taken orally. Mortuiccio would not have purchased this PE Product had Johnson & Johnson informed him of its lack of efficacy in relieving congestion or he would have paid significantly less than he paid insofar as this PE Product was only effective in treating his other symptoms and was not effective in treating sinus pressure and congestion.

237. Upon learning from his attorneys in prior litigation that an FDA Advisory Panel had determined that an active ingredient in TYLENOL® Cold + Flu Severe was ineffective as an oral decongestant, Mortuiccio retained counsel to protect his rights.

238. On April 25, 2024, Mortuiccio caused a Notice of Breach to be sent via U.S. Mail to Johnson & Johnson., advising that they had breached the express and implied warranties they had made to him when he purchased TYLENOL® Cold + Flu Severe because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(c) Mortuiccio Purchased Mucinex Maximum Strength Fast-Max Severe Congestion & Cough

239. In the last three years, Mortuiccio has purchased in New York at least one package containing 6 fluid ounces of Mucinex Maximum Strength Fast-Max Severe Congestion & Cough, a product manufactured and/or labeled by RB.

240. Mortuiccio made this purchase because he wanted medication that contained an active ingredient that would be effective in treating his nasal and/or sinus congestion.

241. Mortuiccio purchased the "Maximum Strength" version of the decongestant because he wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating his nasal and/or sinus congestion.

242. In making his purchase, Mortuiccio relied upon the product packaging and the "Mucinex" brand name to make his purchasing decision—he read on the package that the product was for "Severe" "Congestion & Cough" and that it promised to relieve "Nasal & Chest Congestion." Further, Mortuiccio knew from seeing years of advertising that "Mucinex" was a brand-name for over-the-counter decongestants. He trusted that any product bearing the "Mucinex" brand name would be an effective decongestant.

243. In making his purchase, Mortuiccio was also misled by RB's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Mortuiccio would not have purchased this PE Product had RB informed him of its lack of efficacy in relieving congestion or he would have paid significantly less than he paid insofar as this PE Product was only effective in treating his other symptoms and was not effective in treating sinus pressure and congestion.

244. Upon learning from his attorneys in prior litigation that an FDA Advisory Panel had determined that an active ingredient in Mucinex Maximum Strength Fast-Max Severe Congestion & Cough was ineffective as an oral decongestant, Mortuiccio retained counsel to protect her rights.

245. On April 25, 2024, Mortuiccio caused a Notice of Breach to be sent via U.S. Mail to RB, advising that they had breached the express and implied warranties they had made to him when he purchased Mucinex Maximum Strength Fast-Max Severe Congestion & Cough because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(d) Mortuiccio Purchased Vicks DayQuil™ and NyQuil™ VapoCOOL SEVERE Maximum Strength Cold & Flu + Congestion Relief Liquid Co-Pack

246. In the last three years, Mortuiccio has purchased in New York at least one package consisting of two 12 fluid ounce bottles of "Vicks DayQuil™ and NyQuil™ VapoCOOL SEVERE Maximum Strength Cold & Flu + Congestion Relief Liquid Co-Pack," a product manufactured and/or labeled by P&G.

247. Mortuiccio made this purchase because he wanted medication that contained an active ingredient that would be effective in treating his nasal and/or sinus congestion.

248. Mortuiccio purchased the "Severe" version of the decongestant because he thought his symptoms were or would be "severe," and he wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating his nasal and/or sinus congestion.

249. In making his purchase, Mortuiccio relied upon the product packaging and the "Vicks," "DayQuil" and NyQuil" brand names to make his purchasing decision—he read on the package that the product was for "Severe Cold & Flu + Congestion," and that it promised to relieve "Nasal Congestion" and "Sinus Pressure." Further, Mortuiccio knew from seeing years of advertising that "Vicks" and "DayQuil" and NyQuil" were brand names for over-the-counter decongestants. He trusted that any product bearing the "Vicks," "DayQuil" and NyQuil" brand names would be an effective decongestant.

250. In making his purchase, Mortuiccio was also misled by P&G's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Mortuiccio would not have purchased this PE Product had P&G informed him of its lack of efficacy in relieving congestion or he would

have paid significantly less than he paid insofar as this PE Product was only effective in treating his other symptoms and was not effective in treating sinus pressure and congestion.

251. Upon learning from his attorneys in prior litigation that an FDA Advisory Panel had determined that an active ingredient in "Vicks DayQuil™ and NyQuil™ VapoCOOL SEVERE Maximum Strength Cold & Flu + Congestion Relief Liquid Co-Pack was ineffective as an oral decongestant, Mortuiccio retained counsel to protect his rights.

252. On April 25, 2024 Mortuiccio caused a Notice of Breach to be sent via U.S. Mail to P&G, advising that they had breached the express and implied warranties they had made to him when he purchased Vicks DayQuil™ and NyQuil™ VapoCOOL SEVERE Maximum Strength Cold & Flu + Congestion Relief Liquid Co-Pack because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(e) Mortuiccio Purchased Mucinex Maximum Strength Fast-Max® Day Cold & Flu and Night Cold & Flu

253. In the last three years, Mortuiccio in New York has purchased at least one package consisting of 24 liquid gels of "Mucinex Maximum Strength Fast-Max® Day Cold & Flu and Night Cold & Flu," a product manufactured and/or labeled by RB.

254. Mortuiccio made this purchase because he wanted medication that contained an active ingredient that would be effective in treating his nasal and/or sinus congestion.

255. Mortuiccio purchased the "Maximum Strength" version of the decongestant because he wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating his nasal and/or sinus congestion.

256. In making his purchase, Mortuiccio relied upon the product packaging and the "Mucinex" brand name to make his purchasing decision—he read on the package that the product

was for "Nasal Congestion," and that it promised to relieve "Sinus Congestion" and "Sinus Pressure." Further, Mortuiccio knew from seeing years of advertising that "Mucinex" was a brand name for over-the-counter decongestants. He trusted that any product bearing the "Mucinex" brand name would be an effective decongestant.

257. In making his purchase, Mortuiccio was also misled by RB's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Mortuiccio would not have purchased this PE Product had RB informed him of its lack of efficacy in relieving congestion or he would have paid significantly less than he paid insofar as this PE Product was only effective in treating his other symptoms and was not effective in treating sinus pressure and congestion.

258. Upon learning from his attorneys in prior litigation that an FDA Advisory Panel had determined that the active ingredient in Mucinex Maximum Strength Fast-Max® Day Cold & Flu and Night Cold & Flu was ineffective as an oral decongestant, Mortuiccio retained counsel to protect his rights.

259. On April 25, 2024 Mortuiccio caused a Notice of Breach to be sent via U.S. Mail to RB, advising that they had breached the express and implied warranties they had made to him when he purchased Mucinex Maximum Strength Fast-Max® Day Cold & Flu and Night Cold & Flu because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(f) Mortuiccio Purchased Vicks DayQuil™ and NyQuil™ SEVERE Maximum Strength Cough, Cold & Flu Relief LiquiCaps™ Co-Pack

260. In the last three years, Mortuiccio in New York has purchased at least one package consisting of twelve liquid capsules of "Vicks DayQuil™ and NyQuil™ SEVERE Maximum

Strength Cough, Cold & Flu Relief LiquiCaps™ Co-Pack," a product manufactured and/or labeled by P&G.

261. Mortuiccio made this purchase because he wanted medication that contained an active ingredient that would be effective in treating his nasal and/or sinus congestion.

262. Mortuiccio purchased the "Maximum Strength" version of the decongestant because he wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating his nasal and/or sinus congestion.

263. Mortuiccio purchased the "Severe" version of the decongestant because he thought his symptoms were or would be "severe," and he wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating his nasal and/or sinus congestion.

264. In making his purchase, Mortuiccio relied upon the product packaging and the "Vicks," "DayQuil" and NyQuil" brand names to make his purchasing decision—he read on the package that the product was for "Severe Cold & Flu," and that it promised to relieve "Nasal Congestion" and "Sinus Pressure." Further, Mortuiccio knew from seeing years of advertising that "Vicks" and "DayQuil" and NyQuil" were brand names for over-the-counter decongestants. He trusted that any product bearing the "Vicks," "DayQuil," and NyQuil" brand names would be an effective decongestant.

265. In making his purchase, Mortuiccio was also misled by P&G's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Mortuiccio would not have purchased this PE Product had P&G informed him of its lack of efficacy in relieving congestion or he would

have paid significantly less than he paid insofar as this PE Product was only effective in treating his other symptoms and was not effective in treating sinus pressure and congestion.

266. Upon learning from his attorneys in prior litigation that an FDA Advisory Panel had determined that an active ingredient in Vicks DayQuil™ and NyQuil™ SEVERE Maximum Strength Cough, Cold & Flu Relief LiquiCaps™ Co-Pack was ineffective as an oral decongestant, Mortuiccio retained counsel to protect his rights.

267. On April 25, 2024, Mortuiccio caused a Notice of Breach to be sent via U.S. Mail to P&G, advising that they had breached the express and implied warranties they had made to him when he purchased Vicks DayQuil™ and NyQuil™ SEVERE Maximum Strength Cough, Cold & Flu Relief LiquiCaps™ Co-Pack because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

Pedro Urena

268. Plaintiff Pedro Urena ("Urena") is a citizen of the State and City of New York who resides in the County and Borough of the Bronx.

269. Urena occasionally contracts the common cold and/or seasonal flu. These conditions cause him to experience symptoms such as nasal and/or sinus congestion. He takes multiple over-the-counter oral decongestants for relief from these symptoms that he has purchased from Walgreen's, CVS, and Target as well as a local pharmacy called Cuidamed Pharmacy in the Bronx.

(a) Urena Purchased Alka-Seltzer Plus Severe Cold & Flu

270. Within the last three years, Urena has purchased in New York at least one package of "Alka-Seltzer Plus Severe Cold & Flu" effervescent tablets, a product manufactured and/or labeled by Bayer.

271. Urena made this purchase because he wanted medication that contained an active ingredient that would be effective in treating his nasal and/or sinus congestion.

272. Urena purchased the "Severe" version of the decongestant because he thought his symptoms were or would be "severe," and he wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating his nasal and/or sinus congestion.

273. In making his purchase, Urena relied upon the product packaging and the "Alka-Seltzer" brand name to make his purchasing decision—he read on the label that the product was for "Severe Cold & Flu" and that it promised to relieve "Nasal Congestion." Further, Urena knew from seeing years of advertising that "Alka-Seltzer" was a brand name for over-the-counter decongestants. He trusted that any product branded "Alka-Seltzer" would be an effective decongestant.

274. In making his purchase, Urena was also misled by Bayer's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Urena would not have purchased this PE Product had Bayer informed him of its lack of efficacy in relieving congestion or he would have paid significantly less than he paid insofar as this PE Product was only effective in treating his other symptoms and was not effective in treating sinus pressure and congestion.

275. Upon learning from his attorneys in prior litigation that an FDA Advisory Panel had determined that an active ingredient in Alka-Seltzer Plus Severe Cold & Flu was ineffective as an oral decongestant, Urena retained counsel to protect his rights.

276. On April 25, 2024, Urena caused a Notice of Breach to be sent via U.S. Mail to Bayer, advising that they had breached the express and implied warranties they had made to him when he purchased Alka-Seltzer Plus Severe Cold & Flu because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(b) Urena Purchased Theraflu Daytime Severe Cold Relief Berry Burst Flavor Hot Liquid Powder

277. In the last three years, Urena has purchased in New York at least one package of six packets of Theraflu Daytime Severe Cold Relief Berry Burst Flavor Hot Liquid Powder, a product manufactured and/or labeled by Haleon.

278. Urena made this purchase because he wanted medication that contained an active ingredient that would be effective in treating his nasal and/or sinus congestion.

279. Urena purchased the "Severe" version of the decongestant because he thought his symptoms were or would be "severe," and he wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating his nasal and/or sinus congestion.

280. In making his purchase, Urena relied upon the product packaging and the "Theraflu" brand name to make his purchasing decision—he read on the package that the product was for "Severe Cold Relief" and that it promised to relieve "Nasal and sinus congestion." Further, Urena knew from seeing years of advertising that "Theraflu" was a brand name for over-the-counter medications. He trusted that any product bearing the "Theraflu" brand name would be an effective decongestant.

281. In making his purchase, Urena was also misled by Haleon's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Urena would not have purchased this PE Product had Haleon informed him of its lack of efficacy in relieving congestion or he would have paid significantly less than he paid insofar as this PE Product was only effective in treating his other symptoms and was not effective in treating sinus pressure and congestion.

282. Upon learning from his attorneys in prior litigation that an FDA Advisory Panel had determined that an active ingredient in Theraflu Daytime Severe Cold Relief Berry Burst Flavor Hot Liquid Powder was ineffective as an oral decongestant, Urena retained counsel to protect his rights.

283. On April 25, 2024, Urena caused a Notice of Breach to be sent via U.S. Mail to Haleon, advising that they had breached the express and implied warranties they had made to him when he purchased Theraflu Daytime Severe Cold Relief Berry Burst Flavor Hot Liquid Powder because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(c) Urena Purchased Vicks DayQuil™ SEVERE Maximum Strength, Cold & Flu Daytime Relief LiquiCaps

284. In the last three years, Urena has purchased in New York at least one package consisting of sixteen liquid capsules of "Vicks DayQuil™ SEVERE Maximum Strength Cold & Flu Daytime Relief LiquiCaps," a product manufactured and/or labeled by P&G.

285. Urena made this purchase because he wanted medication that contained an active ingredient that would be effective in treating his nasal and/or sinus congestion.

286. Urena purchased the "Maximum Strength" version of the decongestant because he wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating his nasal and/or sinus congestion.

287. Urena purchased the "Severe" version of the decongestant because he thought his symptoms were or would be "severe," and he wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating his nasal and/or sinus congestion.

288. In making his purchase, Urena relied upon the product packaging and the "Vicks," and "DayQuil" brand names to make his purchasing decision—he read on the package that the product was for "Severe Cold & Flu," and that it promised to relieve "Nasal Congestion" and "Sinus Pressure." Further, Urena knew from seeing years of advertising that "Vicks" and "DayQuil" were brand names for over-the-counter decongestants. He trusted that any product bearing the "Vicks," and "DayQuil" brand names would be an effective decongestant. Urena was also misled by P&G's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Urena would not have purchased this PE Product had P&G informed him of its lack of efficacy in relieving congestion or he would have paid significantly less than he paid insofar as this PE Product was only effective in treating his other symptoms and was not effective in treating sinus pressure and congestion.

289. Upon learning from his attorneys in prior litigation that an FDA Advisory Panel had determined that an active ingredient in "Vicks DayQuil™ SEVERE Maximum Strength Cold & Flu Daytime Relief LiquiCaps was ineffective as an oral decongestant, Urena retained counsel to protect her rights.

290. On April 25, 2024, Urena caused a Notice of Breach to be sent via U.S. Mail to P&G, advising that they had breached the express and implied warranties they had made to him when he purchased Vicks DayQuil™ SEVERE Maximum Strength Cold & Flu Daytime Relief LiquiCaps because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

Kimberly McNulty

291. Plaintiff Kimberly McNulty ("McNulty") is a citizen of the State and City of New York, County and Borough of Bronx.

292. From time to time, McNulty or her eleven-year-old son catch the common cold and/or seasonal flu. These conditions cause them to experience symptoms including nasal and/or sinus congestion. For relief from these symptoms, Plaintiff personally takes and/or administers to her son over-the-counter oral decongestants.

(a) McNulty Purchased up & up Daytime Severe Cold & Flu

293. In the last three years, McNulty purchased Target's up & up Daytime Severe Cold & Flu Softgel medicine from Target in the Bronx, New York, and product manufactured and/or labeled by Target.

294. McNulty made this purchase because she wanted medication that contained an active ingredient that would be effective in treating her nasal and/or sinus congestion.

295. McNulty purchased the "Severe" version of the decongestant because she thought her symptoms were or would be "severe," and she wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating her nasal and/or sinus congestion.

296. In making her purchase, McNulty relied upon the product packaging and the Target "up & up" brand name to make her purchasing decision—she read on the packaging that the

product was intended for "Nasal Congestion and Sinus Pressure." She trusted that any product branded "up & up" would be an effective decongestant.

297. In making her purchase, McNulty was also misled by Target's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. McNulty would not have purchased this PE Product had Target informed her of its lack of efficacy in relieving congestion or she would have paid significantly less than she paid insofar as this PE Product was only effective in treating her other symptoms and was not effective in treating sinus pressure and congestion.

298. Upon learning that an FDA Advisory Panel had determined that the active ingredient in up & up Daytime Severe Cold & Flu Softgel was ineffective as an oral decongestant, McNulty retained counsel to protect her rights.

299. On April 25, 2024, McNulty caused a Notice of Breach to be sent via U.S. Mail to Target Corporation advising that they had breached the express and implied warranties they had made to her when she purchased Target's up & up Daytime Severe Cold & Flu Softgel medicine because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(b) McNulty Purchased Walgreens Multi-Symptom Children's Cold Liquid

300. In the last three years, McNulty purchased Walgreens Multi-Symptom Children's Cold Liquid medicine from Walgreens in the Bronx, New York, a product manufactured and/or labeled by Walgreens.

301. McNulty made this purchase because she wanted medication that contained an active ingredient that would be effective in treating her son's nasal and/or sinus congestion.

302. In making her purchase, McNulty relied upon the product packaging and the "Walgreens" brand name to make her purchasing decision—she read on the packaging that the product was intended for "Stuffy Nose." She trusted that any product branded "Walgreens" would be an effective decongestant.

303. In making her purchase, McNulty was also misled by Walgreens' failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. McNulty would not have purchased this PE Product had Walgreens informed her of its lack of efficacy in relieving congestion or she would have paid significantly less than she paid insofar as this PE Product was only effective in treating her other symptoms and was not effective in treating sinus pressure and congestion.

304. Upon learning that an FDA Advisory Panel had determined that the active ingredient in Walgreens Multi-Symptom Children's Cold Liquid was ineffective as an oral decongestant, McNulty retained counsel to protect her rights.

305. On April 25, 2024, McNulty caused a Notice of Breach to be sent via U.S. Mail to Walgreens Co. advising that they had breached the express and implied warranties they had made to her when she purchased Walgreens Multi-Symptom Children's Cold Liquid medicine because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(c) McNulty Purchased Walgreens Daytime Severe Cold & Flu Maximum Strength

306. In the last three years, McNulty purchased Walgreens Daytime Severe Cold & Flu Maximum Strength medicine from Walgreens in the Bronx, New York, a product manufactured and/or labeled by Walgreens.

307. McNulty made this purchase because she wanted medication that contained an active ingredient that would be effective in treating her nasal and/or sinus congestion.

308. McNulty purchased the "Severe" version of the decongestant because she thought her symptoms were or would be "severe," and she wanted to take the highest possible safe dosage of an active ingredient that would be effective in treating her nasal and/or sinus congestion.

309. In making her purchase, McNulty relied upon the product packaging and the "Walgreens" brand name to make her purchasing decision—she read on the packaging that the product was intended for "Nasal Congestion and Sinus Pressure." She trusted that any product branded "Walgreens" would be an effective decongestant.

310. In making her purchase, McNulty was also misled by Walgreens' failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. McNulty would not have purchased this PE Product had Walgreens informed her of its lack of efficacy in relieving congestion or she would have paid significantly less than she paid insofar as this PE Product was only effective in treating his other symptoms and was not effective in treating sinus pressure and congestion.

311. Upon learning that an FDA Advisory Panel had determined that the active ingredient in Walgreens Daytime Severe Cold & Flu Maximum Strength was ineffective as an oral decongestant, McNulty retained counsel to protect her rights.

312. On April 25, 2024, McNulty caused a Notice of Breach to be sent via U.S. Mail to Walgreens advising that they had breached the express and implied warranties they had made to her when she purchased Walgreens Daytime Severe Cold & Flu Maximum Strength medicine because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(d) McNulty Purchased CVS Health Children's Day + Nighttime Cold, Cough + Congestion Relief Liquid

313. In the last three years, McNulty purchased CVS Health Children's Day + Nighttime Cold, Cough + Congestion Relief Liquid medicine from CVS in the Bronx, New York, a product manufactured and/or labeled by CVS.

314. McNulty made this purchase because she wanted medication that contained an active ingredient that would be effective in treating her nasal and/or sinus congestion.

315. In making her purchase, McNulty relied upon the product packaging and the "CVS" brand name to make her purchasing decision—she read on the packaging that the product was intended relieving congestion.

316. In making her purchase, McNulty was also misled by CVS's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. McNulty would not have purchased this PE Product had CVS informed her of its lack of efficacy in relieving congestion or she would have

paid significantly less than he paid insofar as this PE Product was only effective in treating her other symptoms and was not effective in treating sinus pressure and congestion.

317. Upon learning that an FDA Advisory Panel had determined that the active ingredient in the PE Product was ineffective as an oral decongestant, McNulty retained counsel to protect her rights.

318. On May 3, 2024, McNulty caused a Notice of Breach to be sent via U.S. Mail to CVS advising that they had breached the express and implied warranties they had made to her when she purchased CVS Health Children's Day + Nighttime Cold, Cough + Congestion Relief Liquid medicine because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

(e) McNulty Purchased CVS Health Non-Drowsy Daytime Multi-Symptom Cold/Flu Relief Softgels

319. In the last three years, McNulty purchased CVS Health Children's Day + Nighttime Cold, Cough, + Congestion Relief Liquid Combo Pack from CVS in the Bronx, New York, a product manufactured and/or labeled by CVS.

320. McNulty made this purchase because she wanted medication that contained an active ingredient that would be effective in treating nasal and/or sinus congestion.

321. In making her purchase, McNulty relied upon the product packaging and the "CVS" brand name to make her purchasing decision—she read on the packaging that the product was intended relieving congestion.

322. In making her purchase, McNulty was also misled by CVS's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more

effective at decongesting than placebo when taken orally. McNulty would not have purchased this PE Product had CVS informed her of its lack of efficacy in relieving congestion or she would have paid significantly less than he paid insofar as this PE Product was only effective in treating her other symptoms and was not effective in treating sinus pressure and congestion.

323. Upon learning that an FDA Advisory Panel had determined that the active ingredient in the PE Product was ineffective as an oral decongestant, McNulty retained counsel to protect her rights.

324. On May 3, 2024, McNulty caused a Notice of Breach to be sent via U.S. Mail to CVS advising that they had breached the express and implied warranties they had made to her when she purchased CVS Health Children's Day + Nighttime Cold, Cough, + Congestion Relief Liquid because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

Tatyana Dekhtyar

325. Plaintiff Tatyana Dekhtyar ("Dekhtyar") is a citizen of the State of New York who resides in Brooklyn, New York.

326. From time to time, Dekhtyar catches the common cold or seasonal flu. When she catches a cold or flu, she experiences symptoms such as nasal and/or sinus congestion. She takes over-the-counter oral decongestants for relief from these symptoms.

327. Within the Class Period, Dekhtyar purchased "Advil Sinus Congestion & Pain," a product manufactured and/or labeled by Haleon, from Target, CVS and Walgreens, in Brooklyn New York. Dekhtyar paid for such purchases out-of-pocket.

328. Dekhtyar made these purchases because she wanted medication that contained an active ingredient that would be effective in treating her nasal and/or sinus congestion.

329. In making her purchases, Dekhtyar relied upon the product packaging and the "Advil" brand name to make her purchasing decision—she read on the packaging that the product promised to relieve "Nasal Congestion", "Nasal Swelling" and "Sinus Pressure." In addition, Dekhtyar knew from seeing years of advertising that "Advil" was a brand name for over-the-counter drugs effective at relieving congestion. She trusted that any product named "Advil" would be an effective decongestant.

330. In making her purchases, Dekhtyar was also misled by Haleon's failure anywhere to disclose its superior knowledge that this PE Product is not, in fact, effective at relieving congestion because the ingredient that purportedly "decongests" in the product, phenylephrine, is no more effective at decongesting than placebo when taken orally. Dekhtyar would not have purchased this PE Product had Haleon informed her of its lack of efficacy in relieving congestion or she would have paid significantly less than she paid insofar as this PE Product was only effective in treating her other symptoms and was not effective in treating sinus pressure and congestion.

331. Upon learning from USA Today Article published in September of 2023 that an FDA Advisory Panel had determined that the active ingredient in Sudafed PE was ineffective as an oral decongestant, Dekhtyar retained counsel to protect her rights.

332. On September 26, 2023, September 27, 2023 and May 3, 2024, Dekhtyar caused a notices of breach and violation of consumer protection statutes to be sent to Haleon, advising that it had breached the express and implied warranties it had made to her when she purchased Advil Sinus Congestion & Pain because "the active nasal decongestant ingredient in this product is phenylephrine, which a Food and Drug Administration advisory panel has concluded is ineffective."

VI. TOLLING OF ALL APPLICABLE STATUTES OF LIMITATION

Discovery Rule Tolling

333. Plaintiffs and the other Class members had no way of knowing about Defendants' deception concerning their PE Products. As consumers, they reasonably believed that the phenylephrine contained within the PE Products that Defendants offered for sale could act as a decongestant.

334. Within the time period of any applicable statutes of limitation, Plaintiffs and the other Class members could not have discovered through the exercise of reasonable diligence that Defendants' PE Products were ineffective as advertised.

335. Plaintiffs and the other Class members did not discover and did not know facts that would have caused a reasonable person to suspect that Defendants did not report information within their knowledge about the ineffectiveness of their PE Products.

336. For these reasons, all applicable statutes of limitation have been tolled through the discovery rule for the asserted claims.

Fraudulent Concealment Tolling

337. All applicable statutes of limitation have also been tolled by Defendants' knowing and active fraudulent concealment and denial of the facts alleged herein throughout the time period relevant to this action.

338. Despite their knowledge that Oral PE is not efficacious as a decongestant, Defendants intentionally withheld and never disclosed to consumers that information in any form, other than Johnson & Johnson's belated partial disclosure, discussed above.

339. Rather than disclose the truth about their PE products, Defendants falsely represented these PE Products as ones that would relieve congestion.

340. Absent discovery, Plaintiffs were unaware of, and unable through reasonable investigation to obtain, the true names and identities of those individuals at Defendants' companies responsible for disseminating false and misleading statements to consumers regarding the ineffectiveness of their PE Products. Defendants necessarily are in possession of this information.

341. Plaintiffs' claims arise out of Defendants' fraudulent concealment of the true effectiveness of PE Products and Defendants' representations to consumers regarding this effectiveness.

342. To the extent that Plaintiffs' claims arise from Defendants' fraudulent concealment, there is no one document or communication, and no one interaction, upon which Plaintiffs base their claims. Plaintiffs allege that at all relevant times, including specifically prior to and at the time they purchased their PE Products: Defendants knew, or were reckless in not knowing, of the lack of effectiveness of PE and PE Products; Defendants were under a duty to truthfully disclose the lack of effectiveness based upon a) their exclusive and/or superior knowledge of the lack of effectiveness of PE and PE Products; b) their partial representations about the effectiveness of PE and PE Products, and c) their active concealment of the lack of effectiveness of PE and PE Products. Defendants never disclosed the lack of effectiveness to Plaintiffs or consumers at any time or place or in any manner.

343. Plaintiffs make the following specific fraud allegations with as much specificity as possible absent access to the information necessarily available only to Defendants:

a. **Who:** Defendants actively concealed the true effectiveness of PE from Plaintiffs and the other Class Members, while simultaneously falsely touting the efficacy of their PE Products. Plaintiffs are unaware of, and therefore unable to identify, the names and identities of those specific individuals at Defendants' companies responsible for such decision;

b. **What:** Defendants knew, or were reckless or negligent in not knowing, that PE is an ineffective decongestant starting no later than January 1, 2016;

c. **When**: Defendants concealed material information regarding PE and PE Products, and made representations about PE and PE Products' effectiveness starting no later than January 1, 2016, continuing through the time of sale, and on an ongoing basis, and continuing to this day. Defendants still have not disclosed the full truth about the lack of effectiveness of PE to anyone outside of Defendants' companies. Defendants never took any action to adequately inform consumers about the true nature of the effectiveness of PE, aside from a small disclosure by Johnson & Johnson on its website following the NDAC's September 2023 announcement that PE is ineffective. Defendants continue to deny any knowledge of or responsibility for the ineffectiveness of PE Products;

d. **Where:** Defendants concealed material information regarding the true effectiveness of PE on its products and in online and in physical advertisements. Plaintiffs are aware of no document, communication, or other place or thing, in which Defendants disclosed the truth about the true effectiveness of PE to anyone outside of Defendants' companies. Such information is not adequately disclosed in any sales documents, displays, advertisements, warranties, or disclaimers on Defendants' websites or in Defendants' stores;

e. **How:** Defendants concealed the lack of effectiveness from Plaintiffs and the other Class Members and made misrepresentations about the effectiveness of PE. Defendants promised in their marketing materials and on their products that their PE Products have qualities that they do not have. Defendants actively concealed the truth about the lack of effectiveness of PE from Plaintiffs and the other Class Members, even though Defendants knew about PE's lack

of effectiveness and knew that information about the lack of effectiveness would be important to a reasonable consumer;

f. **Why**: Defendants actively concealed material information and made material misrepresentations about the effectiveness of PE for the purpose of inducing Plaintiffs and the other Class Members to purchase PE Products, and/or pay more for them than they otherwise would. Had Defendants disclosed the truth, for example on their products, in their advertisements or other materials or communications, Plaintiffs and the other Class Members (all reasonable consumers) would have been aware of it and would not have bought PE Products or would have paid less for them.

Estoppel

344. Defendants were under a continuous duty to disclose to Plaintiffs and the other Class members the true character, quality, and nature of their PE Products.

345. Defendants knowingly, affirmatively, and actively concealed the true nature, quality, and character of their PE Products.

346. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

VII. CLASS ACTION ALLEGATIONS

347. Plaintiffs bring this action pursuant to Rules 23(a), 23(b)(2), 23(b)(3), and 23(c)(4) of the Federal Rules of Civil Procedure, individually and on behalf of all others similarly situated.

348. Plaintiffs seek to represent the following Classes:

a. The Nationwide RICO Class

> All natural persons who, from 2016 to the present, purchased an oral nasal decongestant containing phenylephrine, other than for resale, manufactured by Defendants (the "Nationwide RICO Class");

b. The Johnson & Johnson New York Class

All natural persons who, from 2016 to the present, purchased in the State of New York, other than for resale, an oral nasal decongestant containing phenylephrine manufactured by Defendant Johnson & Johnson (the "Johnson & Johnson New York Class");

c. The RB New York Class

All natural persons who, from 2016 to the present, purchased in the State of New York, other than for resale, an oral nasal decongestant containing phenylephrine manufactured by Defendant RB (the "Reckitt Benckiser New York Class");

d. The Bayer New York Class

All natural persons who, from 2016 to the present, purchased in the State of New York, other than for resale, an oral nasal decongestant containing phenylephrine manufactured by Defendant Bayer (the "Bayer New York Class");

e. The CVS New York Class

All natural persons who, from 2016 to the present, purchased in the State of New York, other than for resale, an oral nasal decongestant containing phenylephrine manufactured by Defendant CVS (the "CVS New York Class");

f. The Target New York Class

All natural persons who, from 2016 to the present, purchased in the State of New York, other than for resale, an oral nasal decongestant containing phenylephrine manufactured by Defendant Target (the "Target New York Class");

g. The Walgreens New York Class

All natural persons who, from 2016 to the present, purchased in the State of New York, other than for resale, an oral nasal decongestant containing phenylephrine manufactured by Defendant Walgreens (the "Walgreens New York Class");

h. The P&G New York Class

All natural persons who, from 2016 to the present, purchased in the State of New York, other than for resale, an oral nasal decongestant containing

phenylephrine manufactured by Defendant P&G (the "P&G New York Class");

i. The Haleon New York Class

All natural persons who, from 2016 to the present, purchased in the State of New York, other than for resale, an oral nasal decongestant containing phenylephrine manufactured by Defendant Haleon (the "Haleon New York Class"); and

j. The Walmart New York Class

All natural persons who, from 2016 to the present, purchased in the State of New York, other than for resale, an oral nasal decongestant containing phenylephrine manufactured by Walmart. (the "Walmart New York Class").

349. Excluded from the Classes are: any claims for personal injury or wrongful death; Defendants, and any of Defendants' members, affiliates, parents, subsidiaries, officers, directors, employees, successors, or assigns; the Judges assigned to this case and their immediate family members; and Court staff assigned to this case.

350. This action has been brought and may properly be maintained on behalf of the Classes proposed herein under the criteria of Rule 23 of the Federal Rules of Civil Procedure.

351. Plaintiffs reserve the right before the Court to determine whether certification of other classes or subclasses are appropriate.

352. Certification of Plaintiffs' claims for classwide treatment is appropriate because Plaintiffs can prove the elements of their claims using the same evidence as would be used to prove those elements in individual actions alleging the same claims.

353. This action has been brought and may properly be maintained on behalf of the Class proposed herein under the criteria of Rule 23 of the Federal Rules of Civil Procedure.

354. **Numerosity – Federal Rule of Civil Procedure 23(a)(1).** The members of the Classes are so numerous and geographically dispersed that individual joinder of all Class Members is impracticable. Plaintiffs are informed and believe that there are millions of members of the Classes based on the size of the market for decongestant products and Defendants' share of that market. Class Members may be notified of the pendency of this action by recognized, Court-approved notice dissemination methods, which may include U.S. Mail, electronic mail, Internet postings, and/or published notice.

355. **Commonality and Predominance – Federal Rule of Civil Procedure 23(a)(2) and 23(b)(3).** This action involves common questions of law and fact which predominate over any questions affecting individual Class members, including, without limitation:

a. whether Defendants engaged in the conduct alleged herein;

b. whether Defendants' alleged conduct violates applicable law;

c. whether and when Defendants knew that phenylephrine was ineffective as a decongestant;

d. whether Defendants sold PE Products as though they were effective;

e. what measures Defendants took to conceal the truth about their PE Products;

f. Defendants' duty to disclose the truth about their PE Products;

g. whether Plaintiffs and the other Class members overpaid for Defendants' PE Products;

h. whether Plaintiffs and the other Class members are entitled to damages, restitution, restitutionary disgorgement, equitable relief, statutory damages, exemplary damages, and/or other relief;

i. whether Plaintiffs and the class are entitled to injunctive relief and the nature of such relief; and

j. the amount and nature of relief to be awarded to Plaintiffs and the other Class members.

356. **Typicality – Federal Rule of Civil Procedure 23(a)(3).** Plaintiffs' claims are typical of the other Class Members' claims because, among other things, all Class members were comparably injured through Defendants' wrongful conduct as described above. Plaintiffs and all Class members suffered monetary damages as a direct proximate result of the same wrongful practices in which Defendants engaged. Plaintiffs' claims arise from the same practices and course of conduct that give rise to the claims of the other Class members.

357. **Adequacy of Representation – Federal Rule of Civil Procedure 23(a)(4).** Plaintiffs are adequate Class representatives because their interests do not conflict with the interests of the other members of the Classes they seek to represent; Plaintiffs have retained counsel competent and experienced in complex class action litigation; and Plaintiffs intend to prosecute this action vigorously. The Classes' interests will be fairly and adequately protected by Plaintiffs and their counsel.

358. **Declaratory and Injunctive Relief – Federal Rule of Civil Procedure 23(b)(2).** Defendants acted or refused to act on grounds generally applicable to Plaintiffs and the other members of the Classes, thereby making declaratory and injunctive relief appropriate, with respect to each Class as a whole.

359. **Superiority – Federal Rule of Civil Procedure 23(b)(3).** A class action is superior to any other available means for the fair and efficient adjudication of this controversy and no unusual difficulties are likely to be encountered in managing this class action. The damages or other financial detriment suffered by Plaintiffs and the other Class members are relatively small compared to the

burden and expense that would be required to individually litigate their claims against Defendants, so it would be impracticable for the members of the Classes to seek redress for Defendants' wrongful conduct individually. Even if Class members could afford individual litigation, such litigation creates a potential for inconsistent or contradictory judgments. It increases the delay and expense to all parties and the court system. By contrast, a class action is suited and intended to manage such difficulties and provide the benefits of uniform and common adjudication, economy of scale, and comprehensive supervision.

360. **Issue Certification – Federal Rule of Civil Procedure 23(c)(4)**. As an alternative to Rule 23(b)(2) and/or 23(b)(3), Plaintiffs seek issue certification under Rule 23(c)(4) of liability issues common to all Class members.

VIII. CLAIMS FOR RELIEF

361. As a matter of state and federal law, Defendants' PE Products are misbranded.

362. The PE Products meet the Federal Food, Drug, and Cosmetic Act (21 U.S.C. ch. 9) ("FDCA's") definition of "drug." *See* 21 U.S.C § 321(g)(1).[57]

363. Federal law, including the FDCA and the FDA's implementing rules and regulations, prohibits Defendants from including false or misleading information in their Products' drug labeling.

364. For example, 21 U.S.C. § 352(a)(1) provides, in pertinent part, that:

> A drug or device shall be deemed to be misbranded—
> (a) False or Misleading Label
> (1) If its labeling is false or misleading in any particular [sic]

[57] "The term 'drug' means . . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals."

365. Consistent with 21 U.S.C. § 352(a)(1), the FDA's rules and regulations implementing the FDCA prohibit false or misleading information in drug labeling.

366. Consistent with 21 U.S.C. § 352(a)(1), the FDA's rules and regulations implementing the FDCA do not and cannot permit, authorize, or require false or misleading information to be included in drug labeling.

367. Federal law also prohibits the introduction into interstate commerce of any misbranded drug. For example, 21 U.S.C. § 331(a) provides, in pertinent part, that defendant may not "[deliver] for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded."

368. Federal law, including the FDCA and the FDA's implementing rules and regulations, requires Defendants not to include false or misleading information in their Products' drug labeling.

369. Further, Federal law, including the FDCA and the FDA's implementing rules and regulations, prohibits Defendants from omitting materials facts from their Products' drug labeling. For example, 21 U.S.C. § 321(n) provides, in pertinent part:

> (n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

370. Consistent with 21 U.S.C. § 321(n), the FDA's rules and regulations implementing the FDCA prohibit omission of material facts from drug labeling which renders that labeling false or misleading.

371. Federal law, including the FDCA and the FDA's implementing rules and regulations, requires Defendants not to omit materially relevant facts from their PE Products' drug labeling.

372. Defendants' conduct in including false and misleading information in their PE Products' drug labeling regarding the efficacy of oral phenylephrine, violated federal law, including the FDCA and the FDA's implementing rules and regulations.

373. Defendants' conduct in omitting material facts in their PE Products' drug labeling regarding the efficacy of oral phenylephrine, which rendered the labels false and misleading, violated federal law, including the FDCA and the FDA's implementing rules and regulations.

374. Defendants' conduct in introducing into interstate commerce misbranded PE Products with drug labeling that includes false and misleading information about oral phenylephrine, violated federal law, including the FDCA and the FDA's implementing rules and regulations.

375. By virtue of their conduct taken in violation of federal law, Defendants also violated New York law, as set forth below in Counts 1-6.

376. The requirements imposed upon Defendants under New York law, set forth below in Counts 1-6, are fully consistent with the requirements imposed upon Defendants under federal law.

377. Both New York law and federal law require Defendants to not include false or misleading information in their PE Products' drug labeling.

378. Both New York law and federal law require Defendants not to omit material facts from their PE Products' drug labeling.

379. At all times, Defendants had the obligation to update their PE Products' drug labeling to not contain false or misleading information regarding the efficacy of oral phenylephrine.

380. At all times, Defendants had the obligation to update their PE Products' drug labeling to not omit material facts about the efficacy of oral phenylephrine.

381. At all times, Defendants had the obligation not to introduce into interstate commerce PE Products that are misbranded.

382. Had Defendants at any time attempted to make such labeling changes, the FDA would not have rejected them.

COUNT 1
Violation of the New York Deceptive Acts and Practices Act
(N.Y. Gen. Bus. Law §349)

383. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1-84 and 131-382 as if fully set forth herein.

384. This Count is brought on behalf of the New York Classes (for the purpose of this Count, "Class" or "Plaintiffs") against the State Law Defendants (for the purpose of this section, "Defendants").

385. Plaintiffs and the other Class members are "person[s] . . . injured by reason of any violation" within the meaning of N.Y. Gen. Bus. Law § 349(h). Defendants are each a "person, firm, corporation or association" within the meaning of N.Y. Gen. Bus. Law §349(b).

386. N.Y. Gen. Bus. Law § 349 ("GBL § 349") prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce." GBL §349(a).

387. In the course of their business Defendants, through their agents, employees, and/or subsidiaries, violated the GBL § 349 by knowingly and intentionally misrepresenting, omitting,

concealing, and failing to disclose material facts regarding the PE Products, including that such drugs inherently lacked efficacy, were no more effective than placebo, and were (and are) not fit to be used for their intended purpose, as detailed above.

388. Defendants had superior access to material facts concerning the nature of their PE Products and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the PE Products lacked efficacy for treatment of nasal and sinus congestion.

389. Defendants had a duty truthfully to disclose PE Products' lack of efficacy because they had superior knowledge of the material fact that phenylephrine was not efficacious for the treatment of nasal and sinus congestion. Nevertheless, Defendants made representations that PE Products were fit to be used for the treatment of nasal and sinus congestion. Each defendant has repeatedly represented—including but not limited to on its product labeling—that PE Products act as nasal decongestants.

390. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding PE Products, including that such products lacked efficacy and are not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive business practices prohibited by GBL § 349, including but not limited to:

(a) representing that the PE Products have characteristics, uses, benefits, and qualities which they do not have;

(b) representing that the PE Products are of a particular standard, quality, and grade when they are not;

(c) advertising the PE Products with the intent not to sell them as advertised; and

(d) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

391. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and other Class members, about the inherently non-efficacious nature of the PE Products.

392. These express affirmations of fact and promises include incomplete instructions that purport, but fail, to include the critical information inside the product label or external to the product label regarding PE Products and the lack of efficacy of phenylephrine. Under New York Law, a "drug…shall be deemed misbranded [i]f its labeling is false or misleading in any particular." N.Y. Educ. Law § 6815(2)(a). Defendants' labeling of the PE Products was false and misleading.

393. It is a violation of GBL § 349 and an unfair trade practice to sell a misbranded product.

394. The facts regarding PE Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and/or failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and other Class members, who consider such facts to be important to their purchase decisions with respect to PE Products.

395. Defendants had an ongoing duty to Plaintiffs and other Class members to refrain from unfair and deceptive practices under the GBL § 349 in the course of their business. Specifically, Defendants owed Plaintiffs and other Class members a duty to disclose all the material facts regarding PE Products, including that such products lacked efficacy and were (and

are) not fit to be used for their intended purpose, as detailed above, because Defendants possessed superior knowledge, intentionally concealed the facts regarding PE Products, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts, including that such products lacked efficacy and were (and are) not fit to be used for their intended purpose.

396. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and other Class members would not have purchased the PE Products, or would have paid less for them, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

397. Defendants' violations present a continuing harm to Plaintiffs and other Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

398. Pursuant to GBL § 349(h), Plaintiffs and the other Class Members seek actual damages or $50 per purchase, whichever is greater, in addition to discretionary three times actual damages up to $1,000 for Defendants' willful and knowing violation of GBL § 349, and an additional civil penalty of $10,000 per elderly person 65 years of age or older because Defendants' conduct was in willful disregard of the rights of elderly persons. GBL § 349-C(2)(b). Plaintiff and Class Members also seek attorneys' fees, an order enjoining the Defendants' deceptive conduct, and any other just and proper relief available under the New York GBL.

COUNT 2
Violation of the New York False Advertising Act
(N.Y. Gen. Bus. Law §350)

399. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1-84 and 131-382 as if fully set forth herein.

400. This Count is brought on behalf of a New York Classes (for the purpose of this Count, "Class" or "Plaintiffs") against the State Law Defendants (for the purpose of this section, "Defendants").

401. Defendants were and are engaged in "conduct of business, trade or commerce" within the meaning of N.Y. Gen. Bus. Law §350.

402. The New York False Advertising Act ("New York FAA") prohibits "[f]alse advertising in the conduct of any business, trade or commerce." N.Y. Gen. Bus. Law §350. False advertising includes "advertising, including labeling, of a commodity . . . if such advertising is misleading in a material respect," taking into account "the extent to which the advertising fails to reveal facts material in the light of . . . representations [made] with respect to the commodity." N.Y. Gen. Bus. Law §350-a(1).

403. Defendants had a duty to disclose the PE products' lack of efficacy because they had superior—indeed exclusive—knowledge of the material fact that phenylephrine was not efficacious for the treatment of nasal and sinus congestion. Nevertheless, Defendants made representations that PE products were fit to be used for the treatment of nasal and sinus congestion.

404. Defendants caused to be made or disseminated through New York and the United States, through advertising, marketing, and/or other publications, statements that were untrue or misleading, and which were known, or which by the exercise of reasonable care should have been known to Defendants, to be untrue and misleading to consumers, including Plaintiffs and other Class members.

405. In the course of their business, Defendants, directly or through their agents, employees, and/or subsidiaries, violated the New York FAA by knowingly and intentionally misrepresenting, omitting, concealing, and/or failing to disclose material facts regarding PE

Products, including that such products inherently lacked efficacy and were (and are) not fit to be used for their intended purpose, as detailed above.

406. Defendants' PE Products are not fit for their intended use because phenylephrine is wholly ineffective when used as intended.

407. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding PE Products, including that such drugs inherently lacked efficacy and were (and are) not fit to be used for their intended purpose, as detailed above, Defendants engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce in violation of the New York FAA.

408. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and/or suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs and other Class members, about PE Products that inherently lacked efficacy and were (and are) not fit to be used for their intended purpose, as detailed above.

409. The facts regarding PE Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs and other Class members, who consider such facts to be important to their purchasing decisions with respect to PE Products.

410. Plaintiffs and the other Class members had no way of reasonably discerning that Defendants' representations were false and misleading or otherwise learning the facts that Defendants had concealed or failed to disclose.

411. Defendants had an ongoing duty to Plaintiffs and other Class members to refrain from false advertising under N.Y. Gen. Bus. Law § 350 in the conduct of their business. Specifically, under N.Y. Gen. Bus. Law § 350-a Defendants were prohibited from failing to disclose all the material facts regarding PE Products in their "advertising, including labeling" so as not to render such advertising "misleading in a material respect" including that such products inherently lacked efficacy and were (and are) not fit to be used for their intended purpose, as detailed above, intentionally concealed the facts regarding PE Products, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts, including that such products inherently lacked efficacy and were (and are) not fit to be used for their intended purpose.

412. Plaintiffs and other Class members were aggrieved by Defendants' violations of the New York FAA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding PE Products, including that such products were inherently defective and not fit to be used for their intended purpose. Specifically, Plaintiffs and other Class members purchased PE Products in reliance on Defendants' misrepresentations, omissions, concealments, and/or failures to disclose material facts regarding PE Products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs and Class members would not have purchased the PE Products, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

413. Defendants' violations present a continuing risk to Plaintiffs and other Class members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

414. As a result of Defendants' violations of the New York FAA, as alleged herein, Plaintiffs and other Class members seek to recover their actual damages or $500, whichever is greater. Because each Defendant acted willfully or knowingly, Plaintiffs and other Class Members are entitled to recover three times actual damages, up to $10,000. Plaintiffs and other Class Members seek an additional civil penalty of $10,000 per elderly person sixty-five years of age or older because Defendants' conduct was in willful disregard of the rights of elderly persons. N.Y. Gen. Bus. Law § 349-C(2)(b). Plaintiffs and other Class Members also seek an order enjoining Defendants' false advertising, attorneys' fees, and other relief that this Court deems just and appropriate.

COUNT 3
Breach of Express Warranty
(N.Y. U.C.C. Law §2-313)

415. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1-84 and 131-382 as if fully set forth herein. This cause of action is brought on behalf of a New York Classes (for the purpose of this Count, "Class" or "Plaintiffs") against the State Law Defendants (for the purpose of this section, "Defendants").

416. Defendants are, and at all relevant times were, "merchants" with respect to the PE Products within the meaning of N.Y. U.C.C. Law §2-104(1) and "sellers" of such products within the meaning of N.Y. U.C.C. Law §2-313.

417. Plaintiffs and the other Class members are, and at all relevant times were, "buyers" within the meaning of N.Y. U.C.C. Law §2-313.

418. In connection with their sale of PE Products, by and through statements in labels, publications, package inserts, and other written materials intended for consumers and the general public, Defendants made certain express affirmations of fact and promises relating to the PE

products to Plaintiffs and the other Class members, including that such PE products were (and are) efficacious for the treatment of nasal and sinus congestion. For example, each product expressly warranted that it could be used to relieve sinus congestion and/or pressure.

419. Defendants marketed, represented, warranted, and sold PE products with these express affirmations of fact and promises in such a way as to induce their purchase or use by Plaintiffs and other Class members, thereby making an express warranty that PE products would conform to Defendants' representations.

420. Defendants' affirmations of fact and promises about PE products, as set forth herein, constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, thus creating an express warranty that the goods would conform to the representations.

421. Each Plaintiff relied on one or more of the Defendants' representations that phenylephrine is efficacious for treatment of congestion.

422. Despite the express warranties Defendants created with respect to PE Products, Defendants delivered PE Products to Plaintiffs and the other Class members that did not conform to Defendants' express warranties that such products were efficacious for the treatment of nasal and/or sinus congestion. Specifically, Defendants breached the express warranties when Defendants represented through their labeling, advertising, and marketing materials that PE Products were efficacious for the treatment of nasal and sinus congestion, and where Defendants omitted in their labeling, advertising, and marketing materials relevant and material facts, which they could have voluntarily included, regarding the scientific consensus that phenylephrine is ineffective as a nasal decongestant.

423. As a direct and proximate result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and other Class members sustained an economic loss in an amount to be determined at trial.

424. Plaintiffs and other Class members seek to vindicate a public right to change pharmaceutical industry-wide standards violated by the Defendants when defendant-entries sold PE Products to Plaintiffs and other Class members that Defendants falsely warranted are efficacious for the treatment of nasal and sinus congestion.

425. As a result of Defendants' breaches of express warranties, as alleged herein, Plaintiffs and other Class members seek an order awarding compensatory and punitive damages, costs, attorneys' fees, and any other just and proper relief available under the law.

COUNT 4
Breach of Implied Warranty of Merchantability
(N.Y. U.C.C. Law §2-314)

426. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1-84 and 131-382 as if fully set forth herein.

427. This cause of action is brought on behalf of the Plaintiffs Erlick, Jones, Mortuiccio, McNulty, and Calzado (for the purpose of this Count, "Class" or "Plaintiffs") against Defendants Target, Walmart, CVS, and Walgreens (for the purpose of this section, "Defendants"). At all relevant times, Defendants were merchants with respect to Phenylephrine-Containing Products that were sold to Plaintiffs and members of the Class and were in the business of selling such products.

428. Plaintiff Erlick of the Class had direct dealings with Defendant Target when she purchased the store-brand PE Product Acetaminophen Day/Night Time Vapor Ice Cold and Flu Relief Caplets – 24ct – up & up™ directly from Target to establish privity of contract between Defendant Target on the one hand, and Plaintiff Erlick on the other hand.

429. Plaintiff Jones of the Class had direct dealings with Defendant Walmart when she purchased the store-brand PE Product Equate Children's Multi-Symptom Cold Liquid, Very Berry, 4 fl oz directly from Walmart to establish privity of contract between Defendant Walmart on the one hand, and Plaintiff Jones on the other.

430. Plaintiff McNulty of the Class had direct dealings with Defendant Target when she purchased the store-brand PE Product up & up daytime Severe Cold & Flu Softgel directly from Target to establish privity of contract between Defendant Target on the one hand, and Plaintiff McNulty on the other hand.

431. Plaintiff McNulty of the Class had direct dealings with Defendant Walgreens when she purchased the PE Products store-brand Walgreens Multi-Symptom Children's Cold Liquid and Walgreens Daytime Severe Cold & Flu Maximum Strength directly from Walgreens to establish privity of contract between Defendant Walgreens on the one hand, and Plaintiff McNulty on the other hand.

432. Plaintiff Calzado of the Class had direct dealings with Defendant CVS when he purchased the PE Products store-brand CVS Health Non-Drowsy Nasal Decongestant PE Maximum Strength and CVS Health Non-Drowsy Sinus PE Pressure, Pain + Cold, directly from CVS to establish privity of contract between Defendant CVS on the one hand, and Plaintiff Calzado on the other hand.

433. Each PE Product sold by Defendants comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used. N.Y. U.C.C. Law §2-314(1) and (2)(c).

434. Defendants breached their implied warranty of merchantability because their PE Products were not in merchantable condition when sold because they were not fit for the ordinary

purposes for which such goods are used in that because phenylephrine is wholly ineffective as a nasal decongestant when taken orally.

435. Further, Plaintiffs and each of the other Class members were the intended beneficiaries of the implied warranties made by Defendants to purchasers of their PE Products.

436. Plaintiffs and the other Class members were damaged by Defendants' breaches of implied warranties of merchantability because they did not receive the benefit of the bargain because they purchased the PE Products to relieve their nasal congestion and the PE products were ineffective to relief their nasal congestion.

437. As a result of Defendants' breaches of implied warranties of merchantability, as alleged herein, Plaintiffs, individually and on behalf of the other Class members, seek an order awarding compensatory and punitive damages, costs, nominal damages, attorneys' fees, and any other just and proper relief available under the law.

COUNT 5
NY Common Law Unjust Enrichment
(In the alternative to Count 3 Express Warranty Claim)

438. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1-84 and 131-382 as if fully set forth herein.

439. This cause of action is brought on behalf of the New York Classes (for the purpose of this Count, "Class" or "Plaintiffs") against the State Law Defendants (for the purpose of this section, "Defendants").

440. Defendants have been unjustly enriched by the Plaintiffs through Plaintiffs' purchasing PE Products from Defendants. Plaintiffs would not have purchased PE Products but for Defendants' concealment of the inefficacy of the PE Products.

441. Plaintiffs unknowingly and unjustly conferred a benefit on Defendants, of which Defendants had superior knowledge since Defendants were aware of the non-efficacious nature of PE Products. Defendants failed to disclose this knowledge and misled Plaintiffs regarding the non-efficacious nature of the PE Products while profiting from this deception.

442. The circumstances are such that it would be inequitable, unconscionable, and unjust to permit Defendants to retain the benefit of revenue that it unfairly obtained from Plaintiffs through the sale of non-efficacious PE Products. This revenue includes the premium price Plaintiffs paid for the PE Products.

443. Plaintiffs, having been damaged by Defendants' conduct and lacking an adequate remedy at law, are entitled to recover or recoup damages as a result of the unjust enrichment of Defendants to their detriment.

COUNT 6
Common Law Fraudulent Concealment

444. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1-84 and 131-382 as if fully set forth herein.

445. This cause of action is brought on behalf of the New York Classes (for the purpose of this Count, "Class" or "Plaintiffs") against the State Law Defendants (for the purpose of this section, "Defendants").

446. Defendants are liable for both fraudulent concealment and omission.

447. Defendants concealed and suppressed material facts concerning the effectiveness of PE and PE Products. Defendants knew that Plaintiffs and the other Class Members would not be able to inspect or otherwise detect the lack of effectiveness in PE Products prior to purchasing the products.

448. Defendants also made numerous voluntary false and misleading statements, described in detail above, to boost confidence in their PE Products, falsely assure purchasers that PE Products were effective at nasal decongesting, and/or falsely state that their products had properties such as "maximum strength" that their products did not have.

449. Defendants concealed the information about PE's effectiveness and made voluntary false statements about PE's effectiveness to prevent harm to Defendants' and their products' reputations in the marketplace, to induce consumers to purchase their PE Products, and to prevent consumers from learning of the ineffective nature of PE Products prior to their purchase. These false representations and omissions were material to consumers, both because they concerned the effectiveness of PE Products and because the representations and omissions played a significant role in consumers' decision to purchase PE Products.

450. As Defendants intended, Plaintiffs and the other Class Members saw Defendants' false statements—made on the products themselves, and in advertisements and promotional materials viewed prior to purchasing PE Products both directly and indirectly. Defendants' misleading voluntary statements about PE Products' effectiveness, as well as Defendants' omissions regarding the truth about the ineffective nature of PE, influenced Plaintiffs and the other Class Members' decisions to purchase PE Products, exactly as Defendants intended.

451. If Defendants disclosed the truth about PE, Plaintiffs and the other Class Members would have seen those disclosures. Indeed, Plaintiffs and the other Class Members would have had multiple opportunities to receive information about PE Products if Defendants chose to disclose the information, including on the product packaging, at pharmacies, in stores, on Defendants' websites, in radio, television, or other online advertisements, brochures, press releases or in other promotional materials, as well as in consumer forums and reviews.

452. Defendants had a duty to disclose the ineffective nature of PE Products because Defendants had superior knowledge and access to the fact that the PE Products were ineffective and Defendants knew the facts were not known to, and were not reasonably discoverable, by Plaintiffs and the other Class Members, since typical members of the public would not have access to or knowledge of scientific information regarding the efficacy of phenylephrine. Defendants knew that, when Plaintiffs and other Class Members purchased PE Products, they were acting on the basis of mistaken knowledge resulting from Defendants' conduct. Defendants' superior knowledge of essential facts rendered all purchases by Plaintiffs and other Class Members without disclosure that phenylephrine is not efficacious at relieving congestion and/or sinus pressure when taken orally inherently unfair.

453. Defendants also had a duty to disclose because they made many general affirmative representations about the effectiveness of PE Products as set forth above, which were misleading, deceptive, and incomplete without disclosure of the additional facts set forth above regarding PE Products' actual effectiveness as nasal decongesting products.

454. The omitted and concealed facts were material because they directly impact the overall effectiveness, value, appeal, and usability of PE Products purchased by Plaintiffs and the other Class Members. Whether a manufacturer's product is of a quality stated by the manufacturer and usable for the purpose it was purchased, are material concerns to a consumer.

455. Defendants actively concealed and suppressed these material facts, in whole or in part, to protect their reputation, sustain their marketing strategy, and avoid expensive recalls that would hurt their brands' image, and did so at the expense of Plaintiffs and the other Class Members.

456. Defendants have still not made full and adequate disclosures. Defendant Johnson & Johnson has shown that Defendants have the authority to voluntarily add appropriate truthful disclosures to their products. Johnson & Johnson put a truthful statement on its website linking to the NDAC's 16-0 vote recommending that the FDA declare phenylephrine ineffective. There is nothing that would have prevented any Defendant from disclosing on its website, in stores, or on product packaging, the scientific consensus that phenylephrine is ineffective.

457. Plaintiffs and the other Class Members were unaware of these omitted material facts and the nature of Defendants affirmative misstatements, and they would not have acted as they did had they known the truth; *i.e.*, they would not have purchased PE Products, or would have paid less for them, had they known that phenylephrine is no more effective than a placebo. Plaintiffs' and Class Members' reasonably relied on Defendants' affirmative misstatements and omissions, and were not positioned to know that PE Products were, in fact, not effective as Defendants claimed them to be.

458. Because of the concealment and misrepresentations, Plaintiffs and the other Class Members sustained damage: they paid value for PE Products that did not reflect the ineffectiveness of PE as a nasal decongestant, and often paid out-of-pocket to purchase alternative nasal decongestants to replace PE Products. Had they been aware of the concealed PE ineffectiveness that existed in PE Products, Plaintiffs would have paid less for their products or would not have purchased them at all.

459. As a direct and proximate result of Defendants' voluntary actions and omissions, Plaintiffs and the Class have suffered and will suffer economic losses and expenses associated with ongoing sales of Phenylephrine-Containing Products.

460. As a direct and proximate result of Defendants' voluntary actions and omissions, Plaintiffs and the other Class Members received goods that have substantially impaired value, and they have suffered incidental, consequential, and other damages, including unreimbursed out-of-pocket costs, an inability to use PE Products for their ordinary and intended purpose and overpayment at the point of sale, in an amount to be determined at trial.

461. Defendants' voluntary acts were done maliciously, oppressively, deliberately, with intent to defraud, and in reckless disregard of Plaintiffs and the other Class Members' rights and well-being, to enrich Defendants.

462. Plaintiffs and the other Class Members seek an order enjoining Defendants' unfair, unlawful, and deceptive practices, as well as declaratory relief. In addition, Plaintiffs and the other Class Members are entitled to recover actual damages, together with appropriate penalties, including but not limited to attorneys' fees, costs of suit, nominal damages, punitive damages, and any other just and proper relief available under the law.

COUNT 7
Violations of the Racketeer Influenced and Corrupt Organizations Act
(18 U.S.C. § 1962(c)-(d))

463. Plaintiffs incorporate the preceding allegations in paragraphs 1-382 as though fully set forth herein.

464. This cause of action is brought on behalf of the Nationwide Class (for the purpose of this Count, "Class" or "Plaintiffs") against the RICO Defendants.

465. Plaintiffs and each of the other Class members are "persons" within the meaning of 18 U.S.C. §1961(3), and each is a "person injured in his [or her] business or property" by reason of the RICO Defendants' violations of RICO within the meaning of 18 U.S.C. §1964(c).

466. At all relevant times, each RICO Defendant has been a "person" within the meaning of 18 U.S.C. §1961(3) because each was capable of holding "a legal or beneficial interest in property."

467. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. §1962(c).

468. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. See 18 U.S.C. §1962(d).

469. Each RICO Defendant engaged in numerous acts of mail and wire fraud in furtherance of the scheme to defraud. *See* 18 U.S.C. §1341 (mail fraud) and §1343 (wire fraud).

470. Each RICO Defendant is a participant in the multi-billion-dollar pharmaceutical drug industry and has been a manufacturer and marketer of OTC oral nasal decongestant products. Each RICO Defendant knew that American consumers would not purchase their oral phenylephrine products if these products were worthless as nasal decongestants.

471. Each RICO Defendant also knew that American consumers would not be able to purchase their oral phenylephrine products if the FDA removed phenylephrine from its status as a safe and effective active ingredient in OTC oral nasal decongestant products.

472. As described above, when challenges to oral phenylephrine's effectiveness at a 10mg dose were raised by consumers and a Citizen Petition was submitted to FDA in February 2007, the RICO Defendants understood that their industry collectively stood to lose more than a billion dollars of revenue *each year* if U.S. consumers were no longer buying their OTC PE Products.

473. In or about late 2006, the RICO Defendants banded together, and through an enterprise facilitated by the CHPA, began recklessly to conspire to keep PE Products on the shelves, even in the face of clear red flags and mounting scientific evidence that such products were no better than placebo.

474. By at least 2016, the RICO Defendants knew that any representation that PE Products were effective at decongesting was baseless and false. By that time, new scientific evidence had established that PE Products do not work as oral nasal decongestants, as described above.

475. But rather than tell the truth, the RICO Defendants used their association through CHPA to defraud the American public by falsely and deceptively maintaining that oral phenylephrine works as a nasal decongestant. The CHPA became a front for the RICO Defendants to provide the patina of legitimacy and industry-wide scientific effort.

476. As part of their scheme, the RICO Defendants caused the CHPA to inundate the FDA with numerous baseless and deceptive statements in submissions asserting oral phenylephrine is effective. At the same time, the CHPA issued misleading press releases aimed directly at consumers.

477. This two-pronged-approach: misleading submissions to regulators and false statements to the public, was designed to: (a) delay an FDA review that would, given the science, result in the ultimate removal of PE Products from the market; and (b) mislead the public into buying as many of these products as possible, irrespective of the fact that the PE Products do not work.

478. The RICO claims are for compensatory damages on behalf of American consumers who purchased PE Products from the RICO Defendants because of the RICO Defendants'

interstate, nationwide scheme to defraud. The PE Products they sold were worthless as nasal decongestants. Nevertheless, to this day, the RICO Defendants continue marketing and selling them.

479. But for the scheme to defraud, American consumers would not have purchased PE Products from the RICO Defendants. Consumers and purchasers are not knowledgeable about scientific evidence or the efficacy of OTC drug products, and the typical consumer lacks any ability to uncover the fraud that is occurring. Knowing this, the RICO Defendants exploited and continue to exploit the public's trust, profiting massively, while at the same time delaying and misguiding the FDA's review process to extend the scheme to defraud for years.

480. The RICO Defendants were only able to continue selling these products to American consumers because they associated together as an enterprise through CHPA using this association as a vehicle to further and conceal their scheme to defraud American consumers, undermine new scientific evidence showing oral phenylephrine is not effective, and substantially delay the FDA's review process.

481. The elements of RICO are met here: the RICO defendants came together to conduct the affairs of an Enterprise; they conducted the Enterprise's affairs through a pattern of racketeering activity; and Plaintiffs and the other Class members suffered economic injury "by reason of" the pattern of racketeering activity.

1. The Enterprise

482. At all relevant times, the RICO Defendants used the CHPA as an enterprise, or, in the alternative, formed an association-in-fact enterprise through the CHPA Phenylephrine Task Group and/or with the other RICO Defendants (referred to herein as the "Phenylephrine Enterprise").

483. At all relevant times, the Phenylephrine Enterprise constituted a single "enterprise" within the meaning of 18 U.S.C. §1961(4), as legal entities, as well as individuals and legal entities associated-in-fact for the common purpose of engaging in the RICO Defendants' unlawful profit-making scheme. CHPA also meets the definition of an "enterprise" as defined in Section 1961(4).[58]

484. At all relevant times, the Phenylephrine Enterprise: (a) had an existence separate and distinct from each RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged; and (c) was an ongoing and continuing organization consisting of legal entities, including the RICO Defendants, all of whom associated for the common purposes set forth above to derive revenues and profits therefrom.

485. Each member of the Phenylephrine Enterprise shared in the bounty generated by the enterprise, *i.e.*, by sharing the benefit derived from substantial sales revenue for PE Products generated by the scheme to defraud Class members nationwide, while concealing the lack of efficacy that threatened sales of all the RICO Defendants' oral phenylephrine products. If any member of the Phenylephrine Enterprise had publicly revealed the truth that there was no reliable scientific evidence that oral phenylephrine was effective, that the Task Group was a sham because it had done no new efficacy studies or critical analysis of the older efficacy studies, and that the Task Group existed solely to deceive the public and delay FDA decision-making, all would lose their revenues and profits from the continued sale of OTC oral PE nasal decongestant products.

486. The Phenylephrine Enterprise coordinated and functioned through the Task Group because the Task Group provided a cover that made the enterprise appear legitimate, purportedly working together to address scientific issues about PE Products. However, the RICO Defendants, through their illegal enterprise, in truth engaged in a pattern of racketeering activity, which

[58] Section 1961 (4) defines "enterprise" to include "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity."

involved a fraudulent scheme to increase revenues for the RICO Defendants and the other entities and individuals associated-in-fact with the enterprise's activities through their fraudulent scheme.

487. The Phenylephrine Enterprise engaged in, and its activities affected, interstate and foreign commerce because it involved commercial activities across both state and national boundaries, such as the marketing, promotion, advertisement, distribution, and sale of PE Products throughout the country and beyond, and the receipt of monies from the sale of the same, as well as public statements and submissions by the Task Group.

488. Within the Phenylephrine Enterprise, there was a common communication network by which co-conspirators shared information on a regular basis via both the Task Group and through other avenues (that involved private communications between the defendants that are not accessible before discovery). The Phenylephrine Enterprise used this common communication network for the purpose of coordinating efforts to undermine attempts to challenge the effectiveness of oral phenylephrine nasal decongestant products.

489. Each participant in the Phenylephrine Enterprise had a systematic linkage to others through CHPA membership, financial ties, and continuing coordination and funding of activities, including through CHPA. Through the Phenylephrine Enterprise, the RICO Defendants functioned as a continuing unit with the purpose of furthering the illegal scheme and their common purposes of increasing their profits and revenues.

490. The RICO Defendants participated in the operation and management of the Phenylephrine Enterprise by directing its affairs. While the RICO Defendants participated in, and are members of, the enterprise, they have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

491. Each RICO Defendant exerted substantial control over the Phenylephrine Enterprise, and participated in, operated and/or directed the enterprise, by:

a. Membership in CHPA and participating in the Task Group's activities and/or accessing its information about phenylephrine;

b. manufacturing, promoting, and selling misbranded oral phenylephrine products with false and misleading labels;

c. concealing the lack of the PE Products' efficacy from the public in promotional materials, advertisements, and other documents;

d. making baseless, deceptive and misleading statements about the efficacy of oral PE in communications with regulators, thereby depriving the public of the truth;

e. collecting revenues and profits in connection with the sale of PE Products; and

f. ensuring that the other RICO Defendants complied with the scheme and common course of fraudulent conduct.

492. The RICO Defendants directed and controlled the ongoing organization necessary to implement their RICO conspiracy at meetings about which the RICO Defendants have unique knowledge and through communications in the unique possession of the RICO Defendants.

493. Similarly, because the CHPA does not publicly disclose all of the members who are associated with the Task Group and the RICO Defendants do not publicly disclose when they communicate, the RICO Plaintiffs cannot fully know the full extent of each individual corporate entity's involvement in the wrongdoing prior to having access to sufficient discovery on this point.

2. The Pattern of Racketeering: Mail and Wire Fraud

494. To carry out their schemes to defraud, the RICO Defendants, each of which is a person associated-in-fact with the Phenylephrine Enterprise (and is a member of CHPA and, on information and belief, the Task Group), did knowingly conduct or participate, directly or indirectly, in the conduct of the affairs of the Phenylephrine OTC Nasal Decongestant Enterprise

through a pattern of racketeering activity within the meaning of 18 U.S.C. §§1961(1), 1961(5) and 1962(c), and which employed the use of the mail and wire facilities, in violation of 18 U.S.C. §1341 (mail fraud) and §1343 (wire fraud).

495. From 2007 to the present, each RICO Defendant has worked to execute a scheme to defraud by infiltrating and using CHPA as a vessel for fraud, including by associating to use the Task Group as an enterprise that has operated as a continuing unit through a fraudulent course of conduct, by:

a. coordinating the suppression of information about oral phenylephrine products' lack of efficacy;

b. falsely representing that old clinical trials were scientifically established and sound;

c. falsely representing that new clinical trials were flawed and poorly designed;

d. sharing information on how to assert that phenylephrine is effective in order to carry out a fraud scheme on American consumers;

e. concealing, camouflaging, and prolonging their ongoing scheme to defraud by making representations about their active involvement in the CHPA Task Group as proof of an industry-wide commitment to critically assess and objectively evaluate the science behind oral phenylephrine products (when in fact the opposite is true); and

f. making baseless, deceptive assertions to the FDA designed to conceal the truth and delay the FDA's review of phenylephrine's effectiveness.

496. As alleged herein, the RICO Defendants have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§1341 and 1343). The multiple acts of racketeering activity that the RICO Defendants committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Defendants' regular use of the

CHPA and other avenues of interstate communication and coordination to conceal phenylephrine's efficacy. The RICO Defendants participated in the scheme to defraud by using e-mail, mail, telephone, facsimile, TV, radio, and/or the internet to transmit mailings and wires in interstate or foreign commerce in furtherance of the scheme.

497. The RICO Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through identical concealments, false statements, and material omissions of the lack of efficacy for years.

498. In devising and executing the illegal scheme, the RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud the Plaintiffs and the Class or to obtain money from them by means of materially false or fraudulent pretenses, half-truths, and omissions of material facts. For the purpose of executing the illegal scheme, the RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

499. The RICO Defendants' predicate acts of racketeering (18 U.S.C. §1961(1)) include, but are not limited to:

(1) Mail Fraud: The RICO Defendants violated 18 U.S.C. §1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing their unlawful scheme to manufacture, market, and sell PE Products by misleading consumers and concealing the lack of efficacy, as well as making deceptive statements to regulators.

(2) Wire Fraud: The RICO Defendants violated 18 U.S.C. §1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing their unlawful scheme to manufacture, market, and sell PE Products by misleading consumers and concealing the lack of efficacy, as well as making deceptive statements to regulators.

500. The RICO Defendants (or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of oral phenylephrine drugs, and related documents by mail or a private carrier affecting interstate commerce to wholesalers and retailers nationwide. The RICO Defendants' use of the mails and wires include, but are not limited to, the transmission, delivery, or shipment of the following, which were foreseeably caused to be sent as a result of the RICO Defendants' illegal scheme:

(1) false and misleading labeling and packaging on all oral phenylephrine products sold by the RICO Defendants since at least 2016;

(2) false or misleading sales and marketing materials, including websites, ads, and other materials that omitted oral phenylephrine's lack of efficacy;

(3) documents and communications that facilitated the scheme, including but not limited to, invoices, shipping records, reports, and correspondence; and/or

(4) other documents to be identified in discovery.

501. The RICO Defendants also used the Task Group to make false and misleading statements that were transmitted through mail and wire transmissions. Specifically, the RICO Defendants used the mail and wires while associating through the Task Group to make sham and fraudulent submissions and misleading public statements to the American public and FDA. Those representations were designed to undermine new studies on phenylephrine's efficacy while bolstering old studies that had obvious design flaws, with the ultimate intent and effect of prolonging sales of PE Products by many years even though there was scientific consensus that these PE Products did not decongest. The CHPA submissions and press releases since 2007 are part of a larger reckless and fraudulent course of conduct by the RICO Defendants, and contain numerous false statements, half-truths, and rendered deceptive due to the omission of material

information. Each and every communication between the RICO Defendants and CHPA to coordinate and plan these press releases and submissions to regulators is a separate act of mail or wire fraud.

502. The mail and wire transmissions described herein were made in furtherance of the RICO Defendants' scheme and common course of fraudulent conduct to sell oral phenylephrine products that were worthless as decongestants, which the RICO Defendants knew were false and/or misleading because at least since 2016 they knew the oral phenylephrine products were not effective. Acts in furtherance of such sales were themselves instances of mail and/or wire fraud.

503. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden and cannot be alleged without access to RICO Defendants' books and records. Since the RICO Defendants have not undertaken the conduct described herein in isolation, but as part of a common scheme and conspiracy, they have also committed violations of 18 U.S.C. §1962(d), by conspiring to violate 18 U.S.C. §1962(c). Various other persons, firms, and corporations may have participated as co-conspirators with the RICO Defendants in these offenses and have performed acts in furtherance of the conspiracy for the RICO Defendants and their unnamed co-conspirators throughout the illegal scheme and common course of conduct.

504. The RICO Defendants had knowledge of the fraud and in addition to directly contributing to and conducting the affairs of the enterprise, they also aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

505. For the conspiracy to succeed for so many years, each RICO Defendant and their coconspirators had to agree to implement and use similar devices and fraudulent tactics—specifically, concealing PE's lack of efficacy as a decongestant.

3. Causation and Damages

506. Plaintiffs and the other Class members were the intended victims of the RICO Defendants' fraud scheme. Through this scheme to defraud the RICO Defendants were able to charge more for their products. The RICO Defendants' advertising, marketing and labeling were all created for American consumers to mislead them into continuing to purchase oral phenylephrine products. The RICO Defendants knew and intended that the Plaintiffs and the rest of the Class would incur costs as a result of the fraudulent course of conduct. The RICO Defendants knew and intended that American consumers like Plaintiffs would rely on their misleading and deceptive statements and material omissions.

507. In fact, Plaintiffs, along with the consuming public and others across the United States, relied upon the drug label information and the concealment of material facts. Plaintiffs' and the other Class members' reliance can be inferred and is made obvious by the fact that no reasonable consumer would purchase or pay extra for a PE Product that is worthless at decongesting.

508. The RICO Defendants also knew that they could only continue selling PE Products to American consumers if the FDA kept phenylephrine as an approved active ingredient and the FDA acted on each Citizen Petition challenging oral phenylephrine's efficacy. The RICO Defendants, through the CHPA Task Group, made multiple submissions to FDA with baseless, sham, and deceptive statements, half-truths and concealed information intending to mislead and delay the FDA's review process. The FDA's review was delayed and prolonged for years as a result of an industry-wide fraudulent effort to promote the efficacy of oral phenylephrine.

509. Unbeknownst to the Plaintiffs, the Class, and the FDA, the RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts

constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the RICO Plaintiffs and the other Class members based on the concealment of the truth, as well as misrepresentations and half-truths, while selling PE Products that were worthless as decongestants. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

510. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Defendants at the expense of the RICO Plaintiffs and the other Class members. The predicate acts were committed or caused to be committed by the RICO Defendants through their participation in the Phenylephrine Enterprise and in furtherance of the scheme. The predicate acts were interrelated in that they involved obtaining the Plaintiffs' and the other Class members' money and avoiding the loss of revenues associated with, *e.g.*, reformulating, not selling, or including accurate disclosures regarding the PE Products that are worthless as decongestants.

511. During the formulation, manufacture, marketing, distribution, and sale of the PE Products, the RICO Defendants came across and/or shared information about the material efficacy concerns of phenylephrine, including through CHPA's Task Group. Nevertheless, the RICO Defendants concealed the lack of efficacy in information it provided to the public about oral phenylephrine products.

512. By reason of, and as a result of, the conduct of the RICO Defendants, and in particular as a result of their pattern of racketeering activity, the RICO Plaintiffs and Class members have been injured in their business and/or property in multiple ways, including, but not limited to the purchase price of oral PE Products; overpayment for oral PE Products; and/or other out-of-pocket expenses.

513. The RICO Defendants' violations of 18 U.S.C. §1962(c) and (d) have directly and proximately caused injuries and damages to the RICO Plaintiffs and Class members. The RICO Plaintiffs and the other Class members are entitled to bring this action for three times their actual damages, as well as injunctive/equitable relief, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. §1964(c).

514. As alleged herein, the RICO Defendants knew by at least 2016 that the PE Products were not effective as a nasal decongestant and, without their fraudulent course of conduct, they would have had no ability to continue selling these products to consumers.

515. As a direct and proximate result of the RICO Defendants' false and misleading statements, including those directed at both the general public and the FDA, as well as their concealment, omission, and failure to disclose material facts concerning the lack of efficacy about PE, the RICO Plaintiffs and the Class members suffered damages through their purchases of PE Products, which are ineffective for their stated purpose and therefore worthless as decongestants.

516. But for the RICO Defendants' scheme to defraud and fraudulent course of conduct, the RICO Plaintiffs would not have purchased or have had to pay a premium for PE Products since at least 2016, because no consumer would pay for a product that did not work or pay extra for nothing of value in return.

517. At the time they purchased the RICO Defendants' oral phenylephrine products, the Plaintiffs and the other Class members did not know, and could not have discovered through reasonable diligence, the material facts regarding the lack of efficacy of these products that the RICO Defendants concealed and/or failed to disclose in statements to consumers and the public.

518. The Plaintiffs and other Class members were the ultimate intended targets of the fraud scheme, as the RICO Defendants marketed these products to consumers and included

packaging and labeling information designed to mislead and cause consumers to purchase these products. Had the RICO Defendants disclosed the true facts regarding the lack of efficacy of oral phenylephrine products, the RICO Defendants would not have been able to sell these products or would have been unable to charge the same price since they were worthless as a decongestant.

519. Thus, as a direct and proximate result of the RICO Defendants' unlawful conduct, the RICO Plaintiffs and the other Class members have suffered damages and out-of-pocket losses, paid for a worthless product, and/or did not receive the benefit of their bargain in that they paid to purchase deceptively marketed products they otherwise would not have purchased. The RICO Plaintiffs' injuries were directly and thus proximately caused by the RICO Defendants' racketeering activities because they were the targets of the scheme to defraud, and the fraud scheme was the logical, substantial, and foreseeable cause of the RICO Plaintiffs' injuries. But for the RICO Defendants' false and misleading statements, as well as the omission of material fact in statements to consumers and the public, the RICO Plaintiffs would not have lost money or property.

520. The RICO Plaintiffs and the other Class members have suffered a concrete and particularized harm that is actual and/or imminent, and that is fairly traceable to the RICO Defendants' unlawful conduct. A favorable decision by this Court is likely to redress the injuries suffered by the RICO Plaintiffs and the other Class members.

521. The RICO Plaintiffs are the only harmed individuals or entities, and there are no other plaintiffs better suited or able to seek a remedy for the economic harms at issue here. Indeed, wholesalers and retailers who purchased oral phenylephrine products made their purchases for resell at a profit, and thus these entities have suffered no concrete harm and have no standing to bring RICO claims against any of the RICO Defendants. By contrast, the Plaintiffs and the other

Class members are the end purchasers for use who were the targets of the scheme to defraud, and they all paid money to buy a product for use that did not work. Thus, they are the only victims of the scheme to defraud and conspiracy with standing to bring viable RICO claims.

IX. REQUEST FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of the other Class members, respectfully request that the Court enter judgment in their favor and against Defendants, as follows:

A. Declaring that this action is a proper class action, certifying the Classes as requested herein, designating Plaintiffs as Class Representatives, and appointing Plaintiffs' Interim Class Counsel as Class Counsel;

B. Awarding Plaintiffs' and the other Class members' damages, including but not limited to nominal damages, punitive damages, statutory damages, treble damages, and costs in an amount to be determined at trial;

C. Granting injunctive relief, including, but not limited to:

1. Requiring Defendants to fully disclose their knowledge of the efficacy (or lack thereof) of their Decongestant Products;

2. Requiring Defendants to disgorge their profits from the sales of their Decongestant Products;

3. Requiring Defendants to pay restitution;

D. Ordering Defendants to pay pre- and post-judgment interest on all amounts awarded;

E. Ordering Defendants to pay attorneys' fees and costs of suit;

F. Ordering such other further relief as may be just and proper.

X. JURY DEMAND

Plaintiffs demand a trial by jury for all claims so triable.

Dated: May 3, 2024
Brooklyn, New York

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